DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

PUBLIC MEETING:

ASSESSING CONSUMER PERCEPTIONS OF HEALTH CLAIMS

Thursday, November 17, 2005

9:00 a.m.

Harvey W. Wiley Federal Building
Auditorium
College Park, Maryland

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P R O C E E D I N G S

Welcome and Overview of Meeting

MS. FRASER: Good morning. If everyone could please take a seat? I am Leslye Fraser, the Director of Office of Regulations and Policy here, in the Center for Food Safety and Applied Nutrition, known to most of you as CFSAN. I have the privilege of serving as your moderator and time-keeper for today's public meeting.

Speaking for the entire Center, I would like to welcome you to this Consumer Studies Conference in which FDA and others will present the results of research aimed at assessing consumer perceptions of health claims. We believe we have planned a day that will be interesting and informative to all of us. CFSAN has invited several researchers from government, academia and industry to present their recent experimental findings, describing how consumers react to communications about substance-disease relationships.

Before beginning today, I would like to go

over some housekeeping details. The restrooms are located right outside the door, at the top of the stairs and down the hall on the right as you walk toward the entrance where you came in. Food and drink is not allowed in the auditorium, and we invite you to participate or partake of any refreshments outside in the foyer. Lunch will be from 12:00 to 1:00 p.m. and may be obtained either in the Wiley Cafe, right outside our building, or in College Park on Route 1. There is also the Air Squadron Restaurant that has a buffet, right on Paint Branch Parkway several blocks around the corner.

We will have a 15-minute break in the morning and another 15-minute break in the afternoon. I ask you to return to your seats promptly as we have an ambitious agenda today. I also will ask you to turn off your cell phones or place them in silent mode if you have not done so already.

I now want to turn to the purpose of today's meeting, which is to discuss the findings

from FDA's own and other research that examines consumers' reactions to health claims on conventional foods and dietary supplements. This is not a public meeting to discuss FDA's interim system for communicating the level of scientific support for health claims on conventional foods and dietary supplements, nor is it a meeting to address specific claims for which FDA may have determined it would or would not exercise enforcement discretion. Rather, this meeting is focused on the results of consumer research in this area and any implications of the available research for further consumer studies that may be needed or are already under way by other parties.

FDA intends to use the results of this research, as well as the comments we have received from stakeholders either here at this meeting or in writing, to determine what future actions and/or changes in policy may be appropriate. Toward that end, this morning and the first part of the afternoon primarily will be devoted to presentations of the various consumer studies that

have been undertaken in this area.

To ensure everyone understands the background and underlying basis for the research that has been done, we will begin with three short presentations. The first will be from Louisa Nickerson, from FDA's Office of General Counsel, who will discuss the legal context of consumer research on health claims and other food labeling claims.

She will be followed by Dr. Barbara Schneeman, the Director of CFSAN's Office of Nutritional Product Labeling and Dietary Supplements, who will give a broad overview of FDA's scientific review of qualified health claims.

The third background presentation will be from Dr. Steven Bradbard, the team leader for CFSAN's consumer studies staff within my Office, who will help frame today's presentations by providing an overview of the various research methods used by the investigators you will hear today.

At that point, we will begin the

presentation of the five consumer research studies. After each research presentation, and as time permits, we will allow a few minutes for clarifying questions. That is, if there is something in the presentation that you did not understand, you can ask questions of clarification and only those questions at that time. Following all presentations this afternoon, we have allotted two hours for attendees to make comments to a panel of FDA researchers that relate more broadly to the research that has been done or which you think needs to be done.

Dr. Brenda Derby, the principal investigator for FDA's qualified health claims study, will begin by presenting her research findings. Following that, we will hear from Dr. Pauline Ippolito, the Associate Director of the Bureau of Economics at the Federal Trade Commission; Wendy Reinhardt Kapsak, the Director of Health and Nutrition at the International Food Information Council in Washington, D.C.; Dr. Paula Bone and Dr. Karen France, from West Virginia

University and, last but certainly not least, Dr. Neal Hooker from Ohio State University, regarding their respective consumer studies research.

When you came in you should have received a handout that provides a short biographical sketch of each speaker today and, in the interest of time, I will ask you to read it in lieu of my giving a more detailed introduction. I would, however, like to thank, on behalf of FDA, each of our visiting presenters for taking the time to participate in today's important public meeting.

Following a short break, we will allow attendees two hours to provide comments to our panel of FDA researchers. We ask that your comments focus primarily on recommendations for additional consumer research in the area of health claims. FDA is especially interested in hearing at that time your views regarding other schemes or signals that may effectively communicate to consumers the level of scientific support for health claims, without leading consumers to make erroneous inferences about the claimed

substance-disease relationship and/or other product characteristics. We also are interested in hearing about alternative research methods that can empirically assess the effect or health impact on consumers' perceptions and behavior.

Again, I would like to reiterate that this meeting is focused on research that will assist policy makers, and during this portion of the meeting FDA panelists will be in a listening mode. Neither the panelists nor I are here to speak to the policies regarding health claims that may result from this research.

Lastly, I would like to note that over 20 have signed up to speak in advance in accordance with the procedures in the Federal Register notice announcing this meeting. Those persons will be given an opportunity to provide us comments first. You should have received a list of those speakers as you came in, which includes the order of presentation, and there are two names I need to add that, due to a glitch in our system, we did not get in, and I will give you those names later. We ask

that each speaker limits your comments to five minutes maximum, and I will be monitoring the time to ensure that we can provide an opportunity for as many people as possible to comment. If you are still speaking when I signal to you that your time has elapsed, I ask that you cease speaking within 20 seconds to allow the next speaker a similar opportunity to provide comment to FDA. If there still is time after the speakers who requested an opportunity to speak in advance have made their presentations, we will offer others in attendance an opportunity to provide comments, subject to a time limitation that may be shorter depending on the requested number of speakers.

A transcript will be made of today's meeting's proceedings which will be available for public examination in our dockets. We also will accept written or electronic comments, including all relevant data and information related to the questions and the focus of this public meeting, at our dockets through January 17, 2006.

With that, it gives me great pleasure to

introduce Louise Nickerson, from our Office of General Counsel, to provide an overview of the legal context underlying food labeling claims. Again, welcome and thank you very much for joining us today.

Legal Context of Consumer Research on Health Claims and Other Food

MS. NICKERSON: Good morning. As Leslye Fraser said, I am here to provide some legal context for the consumer research that you are going to hear about today. I would like to emphasize that the purpose of this meeting is to discuss the consumer research that FDA and other organizations have been doing and that the information I am about to provide about legal context is for background only. We are not going to be discussing the legal issues surrounding food labeling claims today. There will be other opportunities for you to comment on how FDA regulates health claims and other food labeling claims.

Well, let's start with what a health claim

is. In FDA parlance, a health claim isn't what one might assume from the ordinary meaning of those words, in other words, any claim about health. We define it more narrowly as an express or implied statement in food labeling about the relationship of a food substance to a disease or health-related condition. Health claims can be made in the labeling of dietary supplements as well as conventional foods, and they require FDA review before they can appear on products in the marketplace. That usually takes place through a petition process.

The key elements of a health claim are, first, a substance, which is a specific food or component of food, whether that food is conventional food or in a dietary supplement form. The second element is a disease or health-related condition, which means damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunctioning, except that nutrient deficiency diseases are not included in this

definition.

Some examples of substance--tuna, which is a specific food and omega-3 fatty acids, which are food components; an example of a disease--colon cancer; an example of a health-related condition, a state of health leading to disease, would be adenomatous colon polyps.

The purpose of health claims was to allow foods, including dietary supplements, to bear certain science-backed claims about disease prevention in their labeling without being regulated as drugs. To that end, in 1990 Congress passed the Nutrition Labeling and Education Act which gave FDA specific authority to permit health claims in the labeling of foods. I say certain scientific science-backed claims about disease prevention because health claims do not encompass claims of absolute prevention. In other words, "take Ultimate tablets and you'll never get cancer." They are simply risk reduction claims.

The reason why, before the NLEA, foods that bore claims even about reducing risk of a

disease ran the risk of being regulated as drugs is that the drug definition includes, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.

To give some examples, a claim that a product "prevents colds" would be a prevention claim and would make a product a drug. "Effective arthritis pain relief" would be a mitigation claim. "Wipes out gout" is a disease cure claim. "Shrinks tumors" is a disease treatment claim. Contrast these types of claims with health claims, which are always phrased in terms of "may reduce the risk of" some disease or health-related condition.

There was a federal appellate case a couple of years ago in which we litigated the scope of health claims, and the court upheld our interpretation that health claims are about reducing the risk of a disease or health-related condition and not about treating, mitigating or curing diseases.

The research being discussed today

involves two different types of health claims, so-called unqualified health claims and qualified health claims.

Unqualified health claims are also referred to as SSA health claims, where SSA stands for significant scientific agreement, and that comes from the Nutrition Labeling and Education Act's standard for FDA to authorize health claims by regulation. It is significant scientific agreement among qualified experts. Sometimes these health claims are referred to as NLEA health claims. FDA authorizes them by regulation. Unqualified is a bit of a misnomer because they actually do contain the word "may" which can be viewed as a qualifier but, actually, that word is intended to indicate that the benefit is risk reduction population-wide as opposed to something that we know will occur in every single person.

Some examples of unqualified health claims that I have put up on the screen are authorized health claims for oat bran and heart disease, and low sodium foods and high blood pressure.

Qualified health claims are health claims that are based on scientific evidence that is credible but that does not meet the significant

scientific agreement standard. These health claims include a disclaimer or other qualifying language to prevent consumers from being misled about the level of support for the claim or other important facts, which could be, for example, conditions of use that are necessary to get the risk reduction benefit. Qualified health claims are considered under FDA's exercise of enforcement discretion, and we do not authorize them by regulation.

Here are some examples of qualified health claims. One is for omega-3 fatty acids and heart disease. The other is for calcium supplements and hypertension or high blood pressure. Qualified health claims came about as a result of several court challenges under the First Amendment to FDA's denial of certain health claims that Congress directed us to consider in the NLEA. The original case that led to qualified health claims is called Pearson versus Shalala, and it was decided by the

D.C. Circuit in 1999.

Today's research is going to involve some other types of labeling claims, specifically, structure/function claims which are claims about how a substance or product affects the structure or function of the human body, an example being that calcium helps build strong bones. Then, dietary guidance statements which are recommendations about dietary patterns and practices that promote health. So, they are more general than health claims are. An example of a dietary guidance statement is "eat plenty of fruits and vegetables every day for good health."

So, why are we interested in consumer research about food labeling claims? Well, first of all, we want to understand how claims in food labeling affect consumer perceptions and, more specifically, what kinds of claims in food labeling have the potential to mislead. Then, as a result of Pearson, we also need to determine whether potentially misleading health claims can be cured by disclaimers or other qualifying language. And,

if the answer is yes, what are the characteristics of an effective disclaimer?

That is my presentation for this morning. Thank you very much.

[Applause]

MS. FRASER: Thank you, Louisa. We will next hear from Dr. Barbara Schneeman, the Director of the Office of Nutritional Product Labeling and Dietary Supplements, also known here as ONPLDS, and she will talk to us about scientific review of the qualified health claims that Louisa just talked about.

Overview of Qualified Health Claims (QHC)

DR. SCHNEEMAN: Thank you, Leslye. Welcome to CFSAN, everyone, who is participating in this meeting. As Leslye has indicated, it is my task to give you a very brief overview of the steps that FDA has taken to develop a framework for the scientific review of qualified health claims.

Just to start first of all with putting some of Louisa's comments into context, certainly we are interested in health and preventing the

incidence of disease or lowering the risk of disease. Qualified health claims then address those steps of how do we intervene to decrease risk of disease and, once something is in the box of treatment of disease, then that is where the drug category comes into play. Certainly, we recognize that either looking at what factors might increase risk or, conversely, to decrease risk we can use biomarkers, and there are several validated biomarkers that are available for assessing how certain dietary factors may reduce risk of certain types of disease.

So, just again to reiterate some of the background, in 1990 the Nutrition Labeling and Education Act was enacted, and this allowed for health claims on foods that were based on significant scientific agreement. In 1994 the Dietary Supplement Health and Education Act was enacted. This then provided for different types of claims as well, structure/function claims, claims of general well being and nutrient deficiency claims. Then, in 1999 we had the beginning of the

Pearson court cases which did recognize the First Amendment protection of commercial speech. It provided for claims that did not meet the standard of significant scientific agreement if they were properly qualified to not mislead consumers. There were several claims that were allowed through the court decision.

So, in October of 2000 FDA began the process of developing its framework for scientific review of qualified health claims. The first step was to revoke the regulation that did not authorize four claims in the original NLEA regulations. As indicated, through the court decisions qualified health claims were subsequently allowed through enforcement discretion for antioxidant vitamins, the 0.8 mg of folic acid, and certain B vitamins related to vascular disease.

After the court decision, but before the implementation of our interim guidelines, there were several claims reviewed and enforcement discretion exercised. The omega-3 fatty acids in heart disease for use of dietary supplements;

selenium in cancer; nuts in heart disease; walnuts in heart disease; and phosphatidylserine related to cognitive dysfunction and dementia.

Then, under former Commissioner Mark McClellan, a task force was convened, with the title of Consumer Health Information for Better Nutrition. This task force released its report in July of 2003, and in that task force report interim procedures were established for the review and evaluation of qualified health claims on both conventional foods and dietary supplements. Contained within that interim guidance is an interim evidence-based ranking system for evaluating scientific data.

At that time, there was also a consumer studies research agenda that was proposed and, clearly, one of the objectives of this meeting is to focus on the results of that consumer studies research agenda. CFSAN continues to have as a high priority developing a regulatory strategy for qualified health claims, but in the interim we are going through the process of reviewing health

claims.

So, we then have the two circumstances, first of all, the claims that are authorized under NLEA that require rule-making by the agency, those that are based on significant scientific agreement, and the agency is still working on those claims. We actually have two under review right now, one about beta-glycan and barley and one about vitamin D and calcium related to osteoporosis. But now we also have qualified health claims, claims that characterize the quality and strength of the scientific evidence if the claim is not based on significant scientific agreement, and those are done through enforcement discretion under the interim guidelines.

Part of our way of thinking about the scientific review process is to think about the continuum of scientific evidence in developing our framework for qualified health claims. It is not that we are looking at different types of scientific evidence for qualified health claims versus SSA claims, but it is more the continuum of

scientific evidence and the strength of that evidence in support of the claim. Obviously, at the highest level one could achieve scientific consensus. Significant scientific agreement is not quite at that high a level but certainly is a high standard and then the world of emerging evidence would allow us to make qualified health claims if suitably qualified.

Some of the language that we have in terms of qualifying language to characterize the level of scientific evidence--in our interim guidance we note that a significant scientific agreement claim would be equivalent to an A-level claim. Then we use the terminology of B-level claims, C-level and D to indicate decreasing levels of comfort relative to the science supporting the claim.

The slide here just gives you examples of the types of qualifying language that we had proposed in the interim guidance. However, it was noted there that the precise language may vary depending on the specific circumstances.

In that interim guidance document there

was a set of steps outlined that the agency goes through in terms of defining the substance and disease relationship consistent with the regulations that Louisa has discussed. We identify the relevant studies. We want to look at the totality of evidence that is available. We classify those studies in terms of the nature of the publication itself--is it a review article? Is it a clinical study? Is it animal data? In vitro data? We rate the studies for quality. We look at factors such as what type of information it gives us in terms of dietary assessment, the statistical analysis used, are appropriate controls used so that we can, in fact, draw reasonable scientific conclusions from the body of evidence.

So, we rate those studies for their quality and then, once we have what we would define as usable information, now we want to rate the strength of that body of evidence relative to the quantity, the quality, consistency and relevance so we can come up with a rank in terms of the nature of the scientific evidence supporting the claim.

Actually, this can now be updated and I am not sure which you have as the handout, whether you have the updated slide or this one, but under the

initiative, the consumer health initiative, we have received 17 petitions for qualified health claims. Many of these petitions contain multiple claims for review. We have had up to 30 claims in one petition, and each one of those claims has to be reviewed for the scientific evidence individually. So, at this point the total number of proposed claims that we have reviewed is actually 75 because we just issued a letter recently. Of those, FDA has considered exercising its enforcement discretion for, I believe it is 16 claims at this point.

In terms of the decisions, they are based on the review of the scientific evidence, and the wording of the claim then reflects the nature of the evidence that has been identified. In some cases our wording may actually describe conflicting data if that is the nature of the evidence that we have identified. Where we have not exercised our

enforcement discretion, it is because we have been unable to identify credible scientific evidence in support of the proposed claim and so that was the decision that we came to.

So, in terms of getting more detailed information, we recommend that one looks at the interim guidance which has been on the web site since that report was published. But we also encourage you to look at the letters that describe our exercise of enforcement discretion. There is a section in each letter that lays out the review of scientific evidence that the agency goes through and gives you our current thinking in terms of the evaluation of that body of scientific evidence. So, it is a great resource in terms of understanding the process. With that, I will turn it back to Leslye. Thank you.

[Applause]

MS. FRASER: Thank you, Barbara. Between Louisa's and Barbara's presentation I think you have at least a background from a legal perspective as well as a scientific perspective of how FDA is

evaluating health claims for conventional foods and dietary supplements. We are very thankful that Barbara was able to join us. She will be leaving shortly to catch a flight for an international meeting. So, if you see her duck out, that is where she is headed. Our next person, and this is the last piece of background information, is Dr. Steven Bradbard. He is within CFSAN's Office of Regulations and Policy, Division of Social Sciences, and he heads up the team of excellent consumer researchers here, in the Center. So, I will ask Steven to come forward and just give an overview of the types of research generally that people in this field have been engaged in.

Overview of Today's Consumer Studies Research

DR. BRADBARD: Good morning. As Leslye mentioned, my name is Steve Bradbard. I am the team leader for the consumer studies staff here, in CFSAN, and I would like to extend a special welcome to today's presenters and to our invited guests on behalf of my team who are a very talented, multi-disciplinary group of professionals who have

close to 200 combined years of social science experience. Alan Levy has 180 of those.

[Laughter]

Over the next few hours you will be hearing several investigators report findings from their recent research on qualified health claims. We realize that for many of you research methodology and data analyses are not part of your everyday work. With that in mind, I want to provide you with an overview of experimental research methods, which I hope will give you a framework for better understanding these study results that you will be hearing today.

I will briefly talk about some commonalities shared by these different studies; then talk about the topic of independent and dependent variables; touch on how researchers interpret data from experiments; and then point out to you the other types of factors that can influence study results.

All of these studies are experiments. They are designed to measure cause and effect relationships.

What I mean by that is consumers are shown a health claim on a food label or ad copy for a product that states a substance-disease relationship. How does that information affect or influence their reactions when they are asked questions about that information? For example, consumers in all of these studies were shown a statement about a substance-disease relationship and then given a question such as, based on this, what is the level of scientific support for the claimed substance-disease relationship? We can measure, based on their ratings of the levels of scientific support, how they react to that statement. So, that is the cause and effect. The manipulation is the information about a substance-disease relationship; the effect is the rating on a measure based on a question that we ask.

Now, again, all of these studies are experiments and there are other research methods that you've probably heard about before, including surveys and focus groups. I have been to meetings where I have heard people using these different

terms interchangeably as though they are all the same thing. In fact, it is very important that you understand that these are very different research methods and that an investigator will select a method based on the objective of a study.

None of these methods in itself is better than another method. The question is which method is the most appropriate to study the question that you are asking. Focus groups--and many of you have possibly participated in or observed a focus group--focus groups provide an in-depth qualitative understanding about the attitudes, beliefs, feelings and motivations that consumers may hold for a particular topic. For example, focus groups would be appropriate to use in order to evaluate consumers' immediate gut level reaction, their thoughts and feelings in response to terms such as 'level of scientific support.' So, in a focus group you might write on a flip chart "what do you immediately think of when you see level of scientific support?" And, you will get the participants pouring their hearts out about level

of scientific support--hopefully. If not, you will prompt them to.

Surveys, in contrast, are used to provide population estimates of awareness and knowledge about a particular topic. For example, if an investigator was interested in estimating the percentage of Americans who have heard of qualified health claims, then a survey would be a useful tool.

Experiments, as I mentioned earlier, are designed to demonstrate cause and effect. So, if a researcher wants to evaluate how consumers react to different ways of qualifying a substance-disease relationship, then an experiment is the most appropriate method. So, no one will leave here today saying they heard interesting things about survey research. Right? Good.

During the presentations today you will likely hear the term independent variables. These refer to the label or ad characteristics that are manipulated in the experiment and then tested. Researchers can vary the way in which the level of

scientific support is presented for a claimed substance-disease relationship. So, by example, they can test how consumers respond when words are used to qualify the level of scientific support. They could also test how consumers react to letter grades as qualifiers and they can evaluate what happens when you use a combination of words and letter grades.

Now, the level of scientific support is just one independent variable that can be studied in this type of experiment. It is also possible to vary the type of statement being tested. For example, how do consumers respond to health claims as opposed to structure/function claims as opposed to dietary guidance statements? The number of claims present on a label can also be manipulated, and you will hear in Dr. Hooker's study that he actually had two claims on his label as opposed to a single claim on the label.

Other variables such as the amount of information provided to consumers before they are asked to make judgments about a claim can be

varied. In Dr. Derby's study you are going to hear about a full information control condition. This involved providing subjects with information ahead of time about the scientific support for the substance-disease relationship, or the lack of support for that relationship, and then evaluating how these newly educated consumers reacted to the claimed statements.

You will also hear the term dependent variables. Sometimes these are also referred to as outcome measures. In a cause-effect relationship the dependent variable is the measured effect. There is a variety of possible outcomes that can be measured, much like there is a variety of independent variables that can be manipulated. You will notice today that not every study uses the same dependent variable. Again, there is no single correct variable; it has to do with what it is that that investigator is looking to get information about.

The information about substance-disease relationships that is communicated by a label claim

or ad copy can affect consumers' judgment and inferences about the level of scientific support for a health claim. All of these studies have some outcome measure related to level of scientific support. But you can also get information from consumers about their perceptions on the likelihood of actually obtaining the claimed health benefit; the overall healthfulness of the product itself; the quality and safety of the product; and their reported intent to purchase the product. All of these, again, are outcome measures.

So, to tie this together, these studies measure consumers' reactions to how the substance-disease relationship is communicated or expressed on a product label or in ad copy. This is accomplished by first showing them information about the substance-disease relationship, the independent variable, and then asking them to provide a rating in response to a specific question. Here is an example, "on a scale of 1 to 5, where 1 means very uncertain and 5 means very certain, how certain are scientists that substance

X may reduce the risk of disease Y?"

Typically, in this type of research the participants will see one or maybe two different claim statements and then answer questions that require that they make judgments or inferences based on the information in those statements. When researchers analyze the ratings that the participants provide on the outcome measures, they make comparisons between the average scores for different groups of subjects. They don't look at any person's individual score. In doing the statistical analysis you compare the average scores for different groups.

For example, a study could have 60 consumers in group 1 see a substance-disease relationship with a strong disclaimer. Just by example, lets say a D-level disclaimer, which is intended to convey that the level of scientific support for that claimed benefit is weak. Sixty different consumers in group 2 can see the same substance-disease statement but with a weaker disclaimer, let's say a B-level disclaimer, which

is intended to convey stronger support for the claimed benefit. All the participants provide individual ratings. We are making group comparisons but they don't all sit together in a room and come up with a single rating for 60 people. They provide their individual ratings and then we take the mean of those ratings. When researchers evaluate the data, they use statistics to determine if the average rating for group 1 on an outcome measure differs significantly from the average rating of group 2 on that same measure and that is how analysis is done.

Of course, there are other possible variables in an experiment, aside from the independent variable and the manipulated variable, that can have an effect on the outcome measure. For example, a person's gender, age, race, educational level, income status, even their geography because people living in certain parts of the country, say, may have different types of reactions to a particular type of message than people in other parts of the country--all of these

things can possibly influence subjects' responses.

You will also hear today from Drs. France and Bone about other factors, such as claim-specific knowledge and attitudes; history of product use; the product-specific benefits; attitudes toward government and industry; and a person's health status. All of these things can affect consumers' judgments and inferences and must be taken into account during the analysis.

This is I think an important reminder because, you know, I have possibly bored you to death saying over and over again substance-disease relationship, substance-disease relationship. We feel strongly--researchers feel strongly that these are communication studies. This is communication research that uses experimental methods to evaluate how consumers react to different ways to discuss substance-disease relationships. That is what this research is about. The focus is not on the actual substance-disease relationship being used, but on the different ways in which this relationship could be presented. Thank you.

[Applause]

MS. FRASER: Thank you, Steve. We are doing very well on time so far, which is good--not

to put pressure on you, Brenda. A couple of things, just housekeeping again or corrections, Barbara mentioned a couple of slides with updated numbers. We will have corrected slides if we can get it all worked out and copied for you either right before lunch or right after lunch.

I mentioned earlier that there were two speakers who had requested an opportunity to speak ahead of time, consistent with the Federal Register, that we inadvertently left off the list. With my apologies, please add as number 20 Dr. Iona Carabin, C-a-r-a-b-i-n, I-o-n-a, M.D. She is President and Medical Director of the Women's Health Sciences Institute. Number 21 will be the Burdock Group and Dr. Berna, B-e-r-n-a, Magnuson would be the speaker, M-a-g-n-u-s-o-n, Ph.D., doctor and toxicologist. So, those will round out the 21 speakers who we will ask to speak first.

With that, we will now get to the heart of

what we are here to discuss, and Brenda Derby, within the Office of Regulations and Policy, under Steve's leadership here, will be discussing the results of FDA's consumer research findings. Brenda?

Presentation of FDA Results

DR. DERBY: Good morning. Now we are going to get to the meat of what everybody came to hear today, and I do have a lot of slides at the beginning where I give an overview to show you the questions that we asked, the disclaimer schemes that we tested, and so forth, and I will try to go through things somewhat quickly so that we can get to the results. But I will also alert you that the detailed report is available on the web, and the last page of your handout shows you the address so, where we don't have charts, you can find those charts on your own at the web site.

As Steve mentioned and we like to emphasize, we have to use health claims, substance-disease relationships, in these studies but that is not what we are interested in. We just

picked ones that seemed reasonable to use in our testing but they are not the focus, and what we are really interested in is assessing the effectiveness of different ways you can go about expressing any substance-disease relationship to indicate the level of scientific support for that claim.

When in shorthand I say health claim, all I am referring to is that simple statement that X may reduce the risk of Y, not all the other things that go with health claims within the regulations and within the law, and unqualified health claim condition means just that, that simple statement. When we have a qualified claim it is that statement plus one of the different ways of qualifying it that I will be showing you in just a moment. We have four disclaimer schemes that we tested in this study. Of course, there is an infinite number that people could think of. We tried to come up with some that seemed reasonable from what people are doing now and have suggested.

The four substance-disease relationships that we used are shown here, and they are in rank

order, A, B, C, D. Calcium may reduce the risk of osteoporosis is a claim that has been through review and is an SSA type of claim.

The other three, although some of them have been through review since we designed the study, at that time had not. So, we just picked levels that seemed kind of reasonable. So, omega-3 fatty acids in the risk of heart disease is our B level claim. Selenium in cancer is a C level, and lycopene and cancer is D level. We looked at four possible disclaimer schemes and they were intended to convey the B, C and D levels of qualified claims, where B would be greater scientific support than C and than D.

The four schemes which have some kind of curious names, but I will show you examples and it will make more sense: point-counterpoint, which is using the words themselves to convey scientific support and where the claim is stated first, followed by the disclaimer statement. The embedded way of expressing it is to start with the disclaimer and then give the statement of the

relationship. Then two report card schemes, one that does it just with text and one that does it with a graphic, and I will show you examples of each one.

Point-counterpoint would be something like "calcium may reduce the risk of osteoporosis," the claim first; "the scientific evidence is promising but not conclusive." In our study that would be a B level disclaimer.

The embedded scheme is a C level, "limited and inconclusive scientific evidence suggests that omega-3 fatty acids may reduce the risk of heart disease." So, here you are getting the disclaimer first.

The text report card tells you about the system: "a diet high in selenium may reduce the risk of cancer. FDA evaluated the scientific evidence and gave it a C rating, based on a scale from A, strongest evidence, to D, weakest evidence."

I should mention that in our experiments we never had an A anywhere. We show it on the

graph that you are going to see here but we did not have a condition in which the A was ever checked because, under our current scheme, an SSA claim does not have anything indicating that it is that type of claim.

As Steve mentioned, this is an experimental design. We did it in shopping malls, five malls across the country and recruited 1,920 adults, an equal number at each site. These are volunteers, and each respondent is assigned to a condition. In our case, they saw two products but they never saw two disclaimers. One of the products they saw would be a control condition, and I will be showing you what those control conditions were in a moment. One of the conditions would have had a disclaimer. And, we counterbalanced the order.

We had to select foods to go with the four claims we selected and we wanted foods that are pretty commonplace and most people would have experience with. So, for the calcium osteoporosis we did a fortified orange juice. For omega-3 we

did tuna but we didn't do the tuna can, we did the foil packs so that you would be able to read the claim; eggs for selenium and spaghetti sauce for lycopene. I will show you pictures. In your handout it is going to be pretty tiny. But one thing I should mention is that the only thing we varied are the claims. The nutrition facts panel is identical across all conditions and all other information is identical.

This one for the orange juice shows a control label where there are no claims at all. So, it just tells you the name of the orange juice. It says "fresh-squeezed" and at the bottom, where you probably can't read it, it has "100 percent pure Florida squeezed orange juice, not from concentrate," and then "64 oz." So, that part would be on every label for orange juice.

For the tuna, this one does have a claim on it. It is a B level claim in this example, and for each condition this is where the claim would be. Except for the full control, they would also have a nutrient content or declaration for the

nutrient that is being mentioned in the claim.

Here is the eggs, and this is the selenium. It would always be in the same spot for each of the different conditions.

And the spaghetti sauce. That is the graphic that you saw earlier where the D is checked. But that is not the only one they see for the spaghetti sauce. They do see a C level claim as well.

We have four key measures of the impact of information on consumers. We call them performance measures. Steve mentioned some of these, the perceived strength of science; the perceived likelihood that you would get the claimed benefit if you ate this food; the perceived likelihood you might get other benefits not specifically mentioned on the claim; and then how important this food would be as part of your total diet. That is the more global rating of people's response to this information.

I will go through each one individually. For the strength of science we have a seven-point

scale, from very uncertain to very certain. They were asked how certain is the scientific evidence that eating foods that contain whichever nutrient it was will reduce the risk of--and then the health condition.

For the claimed benefits we have one multi-part question that was used for both those measures. For the claim relevance it would be whichever one of these is relevant to the health claim, and then the others would be the ones that are other health benefits. So, they are asked this for each product they saw: reduce the risk of having a heart attack, high blood pressure or getting cancer and getting osteoporosis, again, on a seven-point scale, from not at all likely to very likely.

The final measure, the importance as part of your diet is a seven-point scale again, not at all important to very important. The question was worded, how important would this food be as part of a healthy diet for you, emphasizing the total diet aspect of eating this food.

I mentioned we had control conditions. We had quite a few control conditions. We had the no claims condition that you saw on the orange juice

label a moment ago. We have the unqualified health claim statement, X may reduce the risk of Y being the only thing on there. Or, a condition where there was only a content claim or a nutrient declaration but no health claim. All the health claim conditions did include the nutrient claims.

We heard earlier that "may" sometimes has a connotation of being qualified. We have heard that in focus groups with consumers. So, we decided to look at that in this study so we reworded the unqualified health claim statement without the word "may." So, instead of saying "calcium may reduce the risk of osteoporosis," we said "calcium reduces the risk of osteoporosis," still indicating that it is a risk reduction type of claim but getting rid of the "may."

Then we had our full information condition. A quarter of the samples were randomly assigned to one of the four claims, and before they

saw any labels they were asked to read one page. I think the copies are either in your packet or they are certainly upstairs, outside. We tried to write these in such a way that the A, B, C, D claims would convey different levels of scientific support, with the D the most negative, indicating the most weakness in what support there was. They didn't see a disclaimer; they saw the label with just the content declaration, and that nutrient was specifically mentioned in the full information so that they would know that there was a link between what they read and this product.

We identified for our analysis three performance standards to look at the effectiveness of these disclaimer schemes. The first was an obvious one, is there a linear effect? We expect that if it is a B claim it should get a higher rating of scientific support than a C claim or a D claim. So, we were looking to see whether that happens.

Then, what is the effect of a disclaimer of any kind on your perception of scientific

certainty? As you would expect, there should be some relationship there.

Then, do these disclaimers have any effect on how people perceive the product? Because one of the things that is important about food labels as opposed to other places people get information about diet-disease relationships is that it is on a particular product so it is implying something about that product. It is not just about the science. I think we found in earlier research that that comes into play when people are deciding what they think of these claims--does it seem right for it to be on that product? Does this product have the right nutrient? Does that aspect of it seem credible?

So, our questions are do disclaimers convey decreasing levels of scientific support? And, we look for that linear effect. Does the scientific certainty rating change if you have a disclaimer versus not having a disclaimer? We expect it would counteract the effect of an unqualified statement when people do their ratings.

And a comparison we do in the analysis in the reporting is we also compare what is the effect of having a claim versus not having a claim. So, first, do claims make a difference? Then, if claims make a difference, does adding that disclaimer to the claim change people's perceptions? So, we look at the inferences about other benefits than the questions that I mentioned earlier.

Finally the results--this is the only chart you are going to see today. I noticed that in the handout, for some mysterious reason, you don't have the labels on the axes but we have level B, C and D level disclaimers. On this side it is a normalized score of the scientific certainty rating. The nature of our design required us to normalize this, not a scale from 1-7. It is a zero mean and plus/minus one standard deviation.

This green is the text report card and this blue is the graphic report card. Those do what you would expect a disclaimer scheme to do. B is the highest, C is in the middle and D is at the

bottom, and both of those relationships are significant at the 0.02 level or less.

The other two, the point-counterpoint and the embedded that relied on words to convey whether the scientific support was less, are not significantly different and don't have that nice slope that you would want. So, in other words, whatever they read, they gave it similar ratings. They didn't perceive less scientific certainty with a D level claim in words than they did with a B level claim.

So, those didn't work and, as a result, in all the subsequent results I am going to tell you about we dropped the people who were in those two conditions. Since the disclaimer was not conveying different levels of science there is no point having all that noise in your analysis. So, the subsequent analyses are all done just on those people who saw a report card in either a text form or a graphic form.

Because I am trying to cover a lot of information in this fairly short amount of time,

you are only going to see bullets for the rest of them because, as I said, the charts are all in our report online.

I mentioned the two main effects that we are going to be looking at across our measures, whether it is an effect of the health claim itself compared to no claim and then the disclaimer versus an unqualified claim.

When we look at scientific certainty there is a health claim effect. People think the science is more certain when they see an unqualified health claim versus if you ask them about a product that just has a nutrient content claim. This effect is strongest for those nutrients they knew the least about. Earlier, in the recruiting part of the study, we asked people if they were familiar with the four nutrients that are included in our claims, and we found that, as you would expect, virtually everybody has heard about calcium having health effects. Omega-3 was about half. Then you get down to about a third when you are talking about selenium and lycopene, just having that basic

recognition that this may have health effects. So, those less familiar nutrients having an unqualified claim had more of an impact on the reading of the science.

For disclaimers, the presence of the appropriate disclaimer was only effective for the lowest level claim, the D level lycopene claim. Surprisingly, level B and C claims were more positive with a disclaimer than without. So, that was kind of an unexpected finding.

When we look at what they think about the relevant health benefits, the claim is promising. Again, you find people were more positive when they saw a health claim, and more so if it was something less about a nutrient they were less familiar with. But for disclaimers we got no significant differences. So, people rated the relevant health benefit that the claim talks about the same whether or not it was a qualified claim. The disclaimer being there made no difference.

We looked at the potential for some halo effects, people in the past have found that the

presence of a claim on a food product sometimes makes people think it has other good attributes that aren't mentioned. They think it just must be a good food and so they tend to give higher ratings to other questions. We only found that on half of them, two of the four, and those were--let me check, I think it was the B and the D claims, but it was by far the greatest for the less known claim. Again, the disclaimer did not change those ratings of perceived other benefits from this food. It was the same whether or not there was a disclaimer there.

When we looked at health importance, the more global rating, we only had a significant effect for the D level claim, lycopene, where it was more positive when there was a health claim versus not. But for the disclaimer, again, no effect. So, people didn't think it was better or worse for their diet as a result of there being a disclaimer there--no significant differences.

We also looked at what happened when you dropped out the "may" and we got what we sometimes

refer to as a boomerang effect where people were more negative when they saw a claim that didn't have the "may" there, maybe because they are surprised to see it worded that way; that is not how they would have seen it before. Or, they may feel that this is just being a little too strong for what they feel comfortable with because we have seen that in the past. If people think a claim is inappropriate and is stated too strongly, trying to influence them, they may have a negative reaction rather than positive when they see that claim. The exception was the B level claim on scientific certainty and other benefits. People who saw that claim were more positive when the "may" was dropped out.

We compared across all the subjects the unqualified health claim statement versus the nutrient content claim. Again, in the past we found that, to the extent people already know about these things and many of the SSA claims are pretty familiar to people, if you just see a low fat claim or a low sodium claim you don't have

to tell people why that is important. They already know. And, we did find out with the calcium that they already know about calcium so you would get the same results with just a calcium claim as you would with putting the health claim on there because they already see that as a signal of that relationship.

But we got strong impacts for the unfamiliar nutrients regarding scientific certainty and the relevant health benefit and health importance compared to just seeing the nutrient claim. Again, this is probably because they know less about it and so they needed a little additional information to tell them why it mattered.

For the full information, after reading the summary people did give stronger ratings to scientific certainty for the A and B level claims, A being the SSA type of claim, not that it actually was ever labeled as A. And, the negative summaries, the C and D claims, were not significantly different. So, although we were

trying to make them more skeptical of those claims, I think just by virtue of the fact that they were reading so much about it they didn't become more skeptical and their ratings were the same as somebody's seeing an unqualified statement of that claim.

Just to summarize, do disclaimers work? Well, in our study and the disclaimer schemes we looked at, the text only disclaimers were unsuccessful at conveying different levels of scientific support. The report card schemes that gave an easy metric, the A, B, C, D that most people are familiar with was much more helpful but it also sometimes created some surprises, for example, when the B and C level claims were rated more positively than the unqualified or, in effect, A claims. So, because the As aren't there people sometimes think anything you say makes it more positive.

The health claim effects we saw are comparable to what has been found in the past. People tend to be more positive about the food

product and disclaimers don't change that positive view that the health claim creates. They often have stronger effects for things that people know less about. So, if it is giving them some new information, some value added information, it has a stronger impact.

People's prior beliefs, of course, are important and if a claim is perceived as being too strong, stronger than it deserves to be, then it can cause a negative reaction. So, there is no guarantee. Even though health claims in general have a positive effect, if it isn't credible to consumers it could have this boomerang, and any information that is to enhance what people know, even when it is highly qualified, may increase their confidence even when you try not to.

The full report is available online. It has charts and more detail on all these things. That is a cumbersome address but it works. And, that is it.

[Applause]

MS. FRASER: Thank you, Brenda. She has

done a miraculous job of reducing a very detailed and thorough report to a nice, concise presentation. So, I thank her for that. We have about ten minutes to take clarifying questions only, if you want her to explain something about the study or something that she said. If you do, if you would come to one of the two microphones--one is here and one is there, state your name and your organization if that is applicable, and pose your question to Brenda, and we will put her in the dunking booth and see if we can dunk her here. So, are there any questions?

[No response]

Great.

DR. DERBY: I will be around all day.

MS. FRASER: Please, step up to the mike.

MR. EMORD: [Microphone off; inaudible]--let me understand that the data you presented are not conclusive but [inaudible]--?

DR. DERBY: Well, it is never 100 percent conclusive. These are research results. These are consumer ratings. You never hear scientists saying

something is absolute. What you look for is consistency across different studies, across different measures, the pattern of results more than any one question or one result.

MR. EMORD: [Microphone off; inaudible].

PARTICIPANT: Turn the microphone on. We can't hear you.

MS. FRASER: I think the mike is on. You might just need to move a little closer. No?

MR. EMORD: Now it is on. Well, my name is Jonathan Emord and I am with Emord Associates. I have a question for you. I imagine that when someone is asked a question in these surveys the people, of course, would come with preexisting knowledge necessarily from the popular press and other sources that may affect their general understanding of the nutrient-disease relationship or their opinion about it. Were any measures taken to exclude from the testing those who had certain levels of knowledge or understanding about the nutrient-disease relationship?

DR. DERBY: No. The way you control those

kind of individual differences in an experiment is that you randomly assign people to a condition so that is a way to control their personal characteristics. Also, by having the control condition where there is no information and asking the same questions, you get a sense of what the prior knowledge is in the population because if it is a relationship people know more about you will get that in your means.

MR. MORTON: Did you assess any correlation between the extent of preexisting knowledge and the level of the qualified claim? In other words--let me rephrase the question, did the extent of your preexisting knowledge tend to cause one to produce a result that was more consistent with what was expected on your grading system?

DR. DERBY: We did ask them ahead of time for their familiarity. I don't think we have run the model with that variable in there but we could do it.

MR. MORTON: That would be interesting.

DR. DERBY: But given that you have

randomly assigned people, you are kind of washing out what you would find otherwise. In a survey you would be able to do that but in something like this you have put them in different conditions in such a way that I think it would be harder to find that kind of effect.

MR. MORTON: Thank you.

MR. EARL: Robert Earl, with the Food Products Association. Brenda, thank you for your presentation. The question is as a follow-up in moving forward into the future. Can you describe--or perhaps this may be applicable to Steve or Alan as well, what are your plans for taking learnings from this research and looking at your future research projects on health claims, and whether you plan to do anything like that, and what some of the structures are--since I know you have some things in the pipeline related to foods versus substance and other types of things like that may help inform the situation?

MS. FRASER: I will ask Steve to come and talk about some of the research that is currently

being planned. In terms of what we may be doing in follow-up of this specific research, that is in part what the purpose is of this conference today and the comments that we are receiving both orally and in writing to help us shape what are the additional research needs. But Steve can certainly talk about some of the studies we currently have planned and are working through getting cleared.

DR. BRADBARD: Just real quickly, we have a couple of studies that are, as you said, in the pipeline. Dr. Jordan Lin is the principal investigator for one of these studies, and this study is going to be looking at how consumers respond to claims for foods rather than for the substance that is believed to affect the health benefits. For example, how do consumers respond to a claim such as "yoghurt may reduce the risk of osteoporosis" versus "yoghurt which contains calcium may reduce the risk of osteoporosis?"

Another study that we have planned, and Dr. Conrad Choiniere is the principal investigator, and he is looking at some of the recent claims that

FDA has allowed under its enforcement discretion, and we are going to be examining consumers' reactions to the actual claim language that has been allowed for omega-3, for mono unsaturated fatty acids, and for green tea for both conventional foods and dietary supplements.

MS. FRASER: Thank you. You will have the last question and then we can take our 15-minute break.

DR. MAGNUSON: Berna Magnuson, Burdock Group. May I ask a question of clarification from Louisa Nickerson?

MS. FRASER: We really are limiting the clarifying questions just because this is more focused on the research. I would say see Louisa at the break. I think that would be a better use of our collective time. Part of it is that I am trying to see if there are others who want to speak later, if we can save as much time as possible.

With that, I have 10:15 by my watch. We will resume promptly in 15 minutes. Again, the restrooms are at the top of the stairs. Don't

bring the food and drink back in here, but please do eat what is available outside. Thank you very much.

[Brief recess]

MS. FRASER: Please take your seats. We will get started or resume, as the case may be. It gives me great pleasure, and we are very thankful to have Dr. Pauline Ippolito with us, the Associate Director from the Bureau of Economics at the Federal Trade Commission, who will next present the results of FTC's research findings. Thank you.

Federal Trade Commission Research

DR. IPPOLITO: Thank you. I sort of feel like I am in a pit here. People may start throwing things! I should begin by saying that the opinions I express today are my own and not official agency positions.

I assume most people in this audience know this but let me begin with just a little bit of background. The FTC is involved in health claim issues because we regulate food advertising, not food labeling. So, obviously, if you are going to

market your product as a healthy product it is probably going to be on the label and in the ad.

So, we have also been doing research on how to communicate on certain science, and how consumers react to this science, and how we would measure it. So, what I am going to do today is present just a few selected results from that research which has been going on for some time and which has been led by Dennis Murphy of our staff in the Economics Bureau.

The FTC does not have the kind of specific regulations that the FDA has. We govern all advertising to consumers virtually, except for prescription drugs and a few other things. So, we have general principles that apply to ads made for all kinds of products. Those are basically described in two major statements in policy, called the deception statement and the advertising substantiation statement, at the FTC. But basically they say that claims must be truthful and not misleading, and firms must have a reasonable basis for any material claim that a substantial

number of reasonable consumers would take from an ad. I am paraphrasing there.

So, when it comes to claims based on science, the issue is what claim can you make given the state of the science? So, there are two things in play, how strong is the science and what can you communicate to consumers about that science? That is how we get into the issue.

We have been doing research on qualified claims. Two key things that we are interested in are can you communicate uncertain science to consumers, or do consumers assume that the science is basically well established when they see a claim? And, can you communicate different levels of science? As we had begun this process, we were thinking about science that was at least weight of the evidence, that is, taking the body of science as a whole, the weight of the evidence was supportive of the hypothesis of the claim that was being made. With recent court decisions we have had to look deeper into science. Could we communicate less than the weight of the evidence?

As I said, we have been doing this for some time.

The results I am going to talk about today are all based on this template, or pretty much all based on this template. This is a fictitious product, as you can see. It is basically an antioxidant supplement--same picture; same layout. What changes is the text in various treatments. So, we would modify the text and see whether it matters in the consumer measures.

This particular ad--let me go back a minute. We start out to say what do we know about antioxidants in cancers. "Scientists have known for some time about the special health benefits of fruits and vegetables that are rich in antioxidant vitamins like vitamins A, C and E. Eating plenty of these foods can reduce the risk of certain kinds of cancer."

Now, this is the part that changes. "Some medical studies are now suggesting that supplements containing these same antioxidant vitamins may also reduce the risk of cancer." What this means for you--"it looks promising but scientists won't be

sure until longer-term research is completed." Then it goes on to, you know, "eat a good diet."

This is what I am going to label the mildly qualified claim. The qualification is all in positive terms. "Studies are now suggesting;" "it looks promising;" won't be sure until we are done with the rest of the research. So, that is the part that is the mildly qualified claim.

To have a control we did a proof claim, what I am going to label a proof claim. This is a very strong claim. It says "scientists have now proven that supplements containing these same antioxidant vitamins also reduce the risk of cancer. It is a fact now." That is not an SSA claim.

[Laughter]

Now, we deliberately made it strong, maybe stronger than we would like to see, so that we would have a strong anchor against which to test the qualifications. The second claim is the mildly qualified claim which we just talked about. Then we have a qualified claim, what I am calling a

qualified claim, which is a little bit stronger. The top paragraph is the same as the mildly qualified but then it says "it is too early to tell for sure. Some studies have failed to show that these vitamins protect against cancer. Longer-term research is needed." So, it is a bit more negative. "It is too early to tell;" "failed"--bad word, failed. Ad copy people don't like negative words. "Longer-term research is needed." In the earlier study "it looks promising," a positive word; "won't be sure until it is completed." Okay? So, it is a tone distinction, a little more negative. Does it really matter to consumers?

Those were our earliest tests. When the court cases came down and we were looking at the prospect of more qualified science and allowing claims for more qualified science we tried to come up with a more highly qualified disclosure. So, that is what I have here. "Some science suggests" is still the same but then there is a box disclaimer. It says, "there is much scientific debate about whether antioxidant vitamin

supplements reduce the risk of some kinds of cancer. Most studies have failed to show that these vitamin supplements reduce the risk of cancer." So, a much stronger qualification, hopefully, reflecting weaker science. Also, set off in a box, more like a warning than traditional ad copy, again, we thought is a stronger qualification.

Let me give you the questions and let you look at the results while I give you the question. Based on what the ad says or suggests, how sure are scientists about whether taking antioxidant vitamin supplements will reduce the risk of certain kinds of cancer? So, it is asking specifically about supplements. It is asking based on what the ad says or suggests, how sure are scientists.

We asked people to rate on a five-point scale from unsure, which was 1, to sure, 5. These are the mean response rates for the different treatment conditions. The first thing is we are getting the kind of ordered response that you would like to see. As we went from proof to mildly

qualified to qualified to highly qualified you get a systematic reduction in the mean response on how sure are scientists. So, that is good. All the differences are statistically significant.

Now, a proof claim which said it was proven; it is fact, consumers are rating as about somewhat sure. So, there is clearly some discounting going on. They are not taking the literal statement as definitive. That is not an unusual result. Throughout the ad literature, consumers are skeptical of ad claims. You know, it is a selling message. Consumers know that. There is a certain amount of discounting that goes on. We are seeing that here but we are getting the systematic pattern that we were hoping to get.

On the highly qualified box claimer we are getting a mean rating that is just beneath the mid-point of the scale. So, the real question in terms of policy in terms of deception is, is that enough. Is that a low enough rating for a C or D level claim? I don't know the answer to that.

Now, one concern we had was, well, this is

a supplement. Maybe supplements are different. At the time, antioxidants were not that well known and so maybe we are getting some discounting of the proof claim because of those features. It is a supplement and it is an unknown relationship.

So, we also tested that proof language on a claim for a cheese product, a low fat cheese product and the calcium osteoporosis claim which is a very well-known claim, and those are the results for a proof claim for that treatment, and there isn't a significant difference between those two. So, there is some discounting going on just because it is an ad treatment probably.

Now, these are mean results. As a matter of enforcement, when we bring an ad case what we have to establish is that a significant number of people were deceived. So, you are really looking at how many people got a deceptive message. So, another way to look at this data is to look at the right tail, if you will. How many people said they were sure, the scientists were sure, which might be a deceptive message if you aren't in the proof

case. This represents those results.

So, how sure are scientists? The percentage of consumers who responded that they were sure was 58 percent for the proof claim, so another measure that not everybody is taking the literal language literally. Then it drops off quite quickly so that the mildly qualified claim is only 22 percent being sure, and then 10 percent and 15 percent and 5 percent. So, it does appear that most people got the message that the science wasn't sure once we introduced even the mildly qualified language. The cheese result comes in pretty comparably as before.

While we were doing all of this, FDA came into the business and they started proposing language in their consents. So, we had this scheme and we decided to test some of their language in our treatment approach. We were also a bit concerned when we had set up this five-point scale. There is a well-known phenomenon in the literature that a lot of consumers don't like going to the extreme boxes and so, you know, having only a

five-point scale was something we wanted to look at. So, we did some additional testing using a seven-point scale, the same kind of idea, but we went from not at all certain, 1, to very certain, 7.

We wanted to test the FDA language. Since we were doing antioxidants, we decided to try to test the C language. So, this is some "scientific evidence suggests that consumption may reduce the risk of certain kinds of cancer. However, FDA has determined that this evidence is limited and not conclusive." So, that is the point-counterpoint approach.

Then, the report card language, same beginning, "FDA evaluated the scientific evidence and gave it a C rating, based on a scale from A, strongest evidence, to D, weakest evidence." To have a measure back to our older work we also tested the highly qualified box disclaimer that I showed you earlier.

First, in terms of the metric, the highly qualified box disclaimer is again coming out just a

bit below the mid-point of the scale so in that range it doesn't seem to be affecting where it is positioned. The two FDA approaches that we tested are coming in above our box disclaimer, which is where you would expect them to be if it was a C kind of disclosure.

When you look at how many people are being deceived given that we have a seven-point scale, what I am showing you here is people who responded 5, 6 or 7 so the top part of the scale. We are getting quite a number of people who are telling us that the evidence is that strong, which might be a reason for concern if, you know, we were looking at C or D type science.

Let me give you a little bit more detail here. This is the highly qualified box disclaimer. This is the whole distribution of responses. First the good news is that very few people are responding 6 and 7 with that highly qualified box disclaimer. That was a highly qualified disclaimer. I would be surprised if very many advertisers would want to run that kind of

disclaimer. What is a bit disturbing is that quite a few people, a quarter of the sample, are saying somewhat certain at 5. So, that might be a reason for concern.

More broadly, it is clear we don't have a very finely honed message here. We are getting a very disperse distribution, almost uniform if you chop off the right tail. So, it is clear we aren't communicating a tight message to most people. We are getting a lot of variation in our response.

The report card disclosure did a little bit better in the sense that more of the mass moves to the middle. We are beginning to look like a normal distribution here. So, C is communicating middle to people, it appears. The language is more all over the map, as it was in our case, though very few people are doing 6 and 7 again.

One of the concerns we had is how much of this is an ad effect? You know, the fact that we are getting these very dispersed reactions because maybe people have different reactions to advertising. So, to test that we tried, in a

different set of experiments, a lycopene fact sheet which was completely outside an ad context. It was, you know, black and white; lots of words on paper; an information sheet as it was called. You know, it was trying to describe the state of the science. So, "a number of studies have found that people who eat diets rich in tomatoes and tomato products tend to have fewer heart attacks and other heart problems. Scientists have also studied whether some of this benefit may be due to lycopene, which is a nutrient found mostly in tomatoes. So far, we have learned that people with heart disease have less lycopene in their bodies than heart-healthy people do. Some studies have reported beneficial effects on cholesterol in the blood when people take lycopene supplements. But other studies have not found any benefits. At present there are no long-term studies of whether people who take lycopene will actually lower their risk of having a heart attack. Wo we do not know whether there is any benefit from taking lycopene supplements. Carefully controlled and long-term

clinical studies will be needed to answer this question."

So, it was an attempt to be neutral, accurately describe the science at the time--this was a few years ago--outside an ad context. We are getting the same sort of very dispersed kind of reaction. We aren't getting a tightly honed message. People aren't used to these kinds of messages. Maybe they react very differently to them.

So, from our point of view it wasn't the ad effect that was driving those dispersed distributions; it was more the content of the message. That was a sample of some of the things we have done.

So, what are some conclusions I would like to leave you with? Well, qualifying language does change the message consumers take away in our tests. By that, I mean that the mean consumer perceptions of scientific certainty fall with stronger language. That was this picture.

So, this is a somewhat different result

than the FDA treatment in that language alone here affected the take-away but it was very different language than the FDA tested, and it was designed to try to very carefully ratchet up the qualification. In both agency's cases we didn't have top-notch ad copy people doing these tests, designing these messages.

So, I think in terms of future research this is potentially an area we could do some work on, we could use some work on. Are there words that will work is a different question than our words seem to work; their words didn't seem to work. You know, there is room for discussion there on what might work and are there better words. Our copy is long-winded. It was designed with ads in mind. It was designed to really try to do a basic test early on. It is probably not what most people want to use and certainly not on a front label. So, I think this is an area where we could use some more work.

We found pretty strong evidence that even with our very strong claim--proved; it is a

fact--we are getting significant discounting. As we talk about qualified claims, remember what the big policy issue is. In an ideal world we would like consumers to know where there is very strong scientific support for actions they might take as opposed to areas where there is good science but it is not conclusive, but they might want to consider changing their behaviors, and knowing the difference between those two.

We have all been focused on how do you qualify, but the other side of it is how do you make the A claims stronger? And, that is something that could be thought about. Is there a way to essentially certify the class A science somehow that is easy, that is quick, that communicates that this is really some solid science and there isn't much debate about it anymore, as opposed to the other kinds of claims that might be made? So, that is another area that I think we could possibly think about a little bit more seriously.

Then, the third thing that we don't know what to do with, other than try and bring in some

professionals maybe, we are getting very dispersed distributions. We don't have tightly honed messages in the ad copies that we did, for sure. So, you are left with both types of error. You have people who are overstating the certainty of the science, but you also seem to have quite a few people who are understating the certainty of the science when you use the kind of language that we have used. Both types of errors really are problematic in terms of trying to get people to absorb the science that is out there and to change their behaviors in ways that are productive for health. We would like to get cleaner, clearer messages to folks. So, how we do that I think is an important part of what we all should be thinking about.

We do have a couple of public reports. That is on the last slide of the handout. They are both on our web site I believe and we would be happy to mail copies to anybody. Thank you.

[Applause]

MS. FRASER: Thank you. We probably have

about five minutes for any clarifying questions for Dr. Ippolito. Please step to the mike and state your name and affiliation. DR. MURPHY: Dennis Murphy, Federal Trade Commission. I just wanted to mention one fact that will maybe pull together the FDA study and the FTC study a little. We did have a control condition for the ACE vitamin product where we asked people who got no claim whatever what their prior assumption--what do you believe about the state of the science. What was interesting was that that was the lowest score. So, people were coming in with very low prior beliefs about the science, which I was very surprised about. So, the disclaimers are not fighting against a very strong prior belief that there is a certain science. Correct me if I am wrong, Alan, but I believe this is also the consistent result you were finding when people saw a no claim condition. They were quite skeptical.

MS. FRASER: Thank you, Dennis.

MR. EMORD: I guess I would ask you or state the same thing I stated before, that when you

deal with studies you really look at probabilities of outcome and not conclusive evidence.

DR. IPPOLITO: Right, you are looking at testing a hypothesis.

MR. EMORD: So the FDA and the FTC do the same thing.

DR. IPPOLITO: Sure. Let me throw one other hypothesis out there. In terms of the FDA finding that the SSA claim actually scored lower than the B level claims in many of their tests, one difference between the two claims is that in the B and other claims you are talking about the science in the claim. In the A level claim there is no discussion of science. There is no mention that there might be scientific support for this claim; it is just a statement. So, then you ask consumers how strong is the science or, you know, what do scientists think about this science you have given them no basis for answering that question, which either may be an artifact of the measurement or it may be that you haven't persuaded them that there is solid scientific support.

So, again, it goes to this issue of looking at the A claims, as well as the qualifying claims, to try to make sure that people are getting

the message that A claims really are the A claims.

MS. FRASER: Thank you very much. We next are pleased to have Wendy Reinhardt Kapsak, from the International Food Information Council Foundation do a presentation of industry's research in this area.

International Food Information Council Foundation's Research

MS. KAPSAK: Hi. I am very thankful to be here today and would just like to tell all the researchers here that I have had an opportunity to speak to many of you and I am so grateful to you for sharing your findings and insights with us, and I would also like to particularly thank FDA for inviting us here today and for really assisting us with several aspects of this project.

Today I am going to talk about a few things that some of you may or may not be familiar with at the Foundation, just to clarify a little

bit about who we are and where we stand, and also let consumers have a say. So, we will present a lot of the consumer research not just on qualified claims but also other kinds of health claims and then label statements. Then I will go ahead and summarize the findings.

The International Food Information Council is a non-profit organization, located here, in Washington, D.C. The main mission of it is to communicate science-based information on a wide variety of food safety and nutrition topics basically to anyone who is on the front line communicating with consumers every single day so health professionals, media, educators, government officials--again, those people that are focused on communicating with consumers every day. We are funded by the broad-based food, agricultural and beverage industry. What makes us really unique in Washington is that we are not involved in any kind of lobbying or advocacy work so in that sense we are quite unique.

IFIC Foundation is the educational arm of

IFIC and this particular research project actually came through the Foundation. So, a lot of the research that IFIC does is actually on the IFIC Foundations' web site, including an executive summary of this research and there are also some copies that may be being passed around and are in the back as well. There is also a Spanish portion on the web site. Also, other educational initiatives, including the Food Insight Newsletter and many different other IFIC Foundation publications can be found on the web site that are truly the educational arm of IFIC.

As we thought about how to put this project together, and we did consult with FDA at that time just because it was stated that there would be consumer research being done, we wanted to find out could we be helpful; could there be anything that IFIC could add to this discussion. So, in that, we put together several different objectives following some of these discussions, particularly with FDA. We wanted to measure consumer reaction to the FDA proposed four levels

or the schematic of health claims on the basis of the strength of the scientific evidence. How do consumer perceive evidence based on that particular schematic.

But this is the part where FDA looked at a number of different outcome measures and we did as well. One that we have in common is the strength of the scientific evidence where we kind of went above and beyond in that we wanted to also look at the overall perceived healthfulness of the product; how does the claim that is being presented to consumers impact the healthfulness of the product; the perception of the product quality; and the perception of the product safety. Then, would the claim's presence have an impact on purchasing intent.

We also wanted to determine if consumers were able to differentiate between dietary guidance and health claims, and there were a few statements already put up in some of the introductory presentations. Then, we also wanted to examine the impact of structure/function claims and some

alternative language to what was being proposed at the time, and how that then compared to consumers' perceptions between those kinds of claims and the current unqualified claims.

We commissioned Cogent Research, out of Cambridge, Massachusetts for a lot of this research and Cogent, IFIC and FDA all worked together in terms of the survey design and then later on some additional methodology and some additional analysis. I don't want to get into too much--I am more than happy to answer any questions about how we put the survey and everything together. This has been a crazy project and I am surprised I am still living! I mean, really!

[Laughter]

I mean, I am going to spare you a lot of the hurt that I have already endured!

[Laughter]

This is actually one of the largest consumer research projects actually completed at the IFIC Foundation and I don't know if we will ever do another project this large, based on what I

just said. It had over 5,600 participants. Most of our quantitative surveys are around 1,000 folks and this was about 5,600 participants. It was a web-based survey and the data was weighted to match the 2001 U.S. Census data.

There were three products that we tested and two of these were similar to the products that FDA tested, orange juice and then the relationship, calcium and osteoporosis; pasta sauce, lycopene and cancer. These were the two that were similar. Then, this kind of new one which was breakfast cereal and the relationship was trilinium and diabetes. Is anyone here familiar with this? But five percent of the U.S. population is familiar with this relationship.

[Laughter]

So, that speaks to a little bit to it right there. And we did test the awareness of the other two, by the way. We also looked at making sure that definitely an aspect of this project, or a part of this project was really moving in parallel with the FDA study as we looked at some of

the same kinds of tested formats, claim formats, and Brenda mentioned some of those.

The four that were consistent between the IFIC research and FDA were the report card graphic and I will show an example of that graphically so that you can see that; then the report card text where we take the letter grade and essentially put it into the language itself; then other language only claims, claims that don't mention any kind of letter grade at all and these were embedded point-counterpoint.

To show you a little bit about how those looked like, we actually tried, to the best of our ability, to make our report graphic claim very similar to that of FDA's. So, on the left-hand side you see the actual claim and then you see this check-box idea over to the right. So, that is an example. Looking back, you know, it is always in retrospect, our control actually did include a nutrient content claim. So, I just wanted to make it very clear up front that that was a slight difference.

The report card text, here you see that the claim language, very long claim language, is actually listed at the bottom of the label here,

and you can see that this component, in this case lycopene, may reduce the risk of disease and then, again, the language that the FDA was also testing. FDA evaluated the scientific evidence and gave it a B rating based on a scale of A, strongest evidence to D, weakest evidence. So, the graphic included just what it says, a graphic or a check box, and then the text took the letter and put it into the language of the claim.

Then we have truly language only claims that don't mention a letter grade at all embedded where the qualifier essentially is given up front, in the very beginning, promising but not conclusive evidence suggests.

Or then, point-counterpoint where it gives the actual statement of the diet-disease relationship but then there is a second statement that says the scientific evidence is promising but not conclusive.

I mentioned that we also looked at structure/ function language, and we did that also for the three products that I mentioned before. So, the calcium and orange juice example also helps promote bone health; lycopene helps maintain prostate health. That was on the pasta sauce

example. Then the breakfast cereal, trilinium helps maintain a health blood sugar level. I did go ahead and run some of these by someone over at FDA, just to see are you okay with these in terms of testing them and they said they seemed pretty reasonable for what we were doing. We also tested some dietary guidance statements and I will go ahead an mention that in a later part of the presentation.

Now I am going to just go ahead and briefly just go over the top line findings. We repeat them at the end but we will also look at them individually. First off, this was mentioned in one of the earlier presentations, it is really, really difficult for us to essentially try to only look at one facet of what could be impacting

consumers' let's say, critical evaluation of a particular claim. So, the claim type, whether we are talking about embedded or graphic, whichever, claim level, A through D in this case, and/or the perceptions of the raw product--do I feel orange juice is health? Is that a healthful product? Or, am I aware, for example, that lycopene may somehow impact prostate health? All of these things, among many others which we are going to hear this afternoon, can really impact how a consumer perceives or is making a critical judgment about a claim and its believability.

So, it is really difficult. When we are trying to look at these things in isolation it is really difficult to make some of those points that have been made really conclusive results about any particular one of these outcome measures.

But, to move forward, consumers have difficulty distinguishing among four levels of scientific evidence, especially with language only claims. Again, that is that point-counterpoint or embedded claim where there is no mention of a

letter grade whatsoever. So, consumers have difficulty distinguishing among those four levels.

Thirdly, consumers can distinguish among four levels using a report card graphic, and we might expect that and we will get into that a little bit more, just based on what we already know about what A, B and C and D have meant to us in our education. But, unfortunately, with this particular schematic or system or claim format we really did see some negative effects observed with consumer perception of product healthfulness, quality, safety and purchase intent. This was seen in various instances with the report graphic, as well as the report card text. So, this idea of trying essentially in this framework to use a really simple symbol or way of trying to express the level of science, while it was helpful in some ways, was actually misleading consumers in other ways.

Finally, consumers rate the scientific evidence and other attributes of a product containing an unqualified claim similar to that of

products containing either a structure/function claim or a dietary guidance statement. So, basically they were rating these particular statements very similarly with regard to strength of the scientific evidence.

So, we mentioned the first finding and I will let others speak more to this in the afternoon. But we can't look at each of these things in isolation. In fact, claim type, claim level, perception of the overall product and then the awareness of the diet-disease relationship, among many others, all impact critical evaluation of a claim or label statement, or perhaps then also ad copy.

So, now as we get more into the meaty part of our findings, we will go ahead and look at them individually. Consumers have difficulty distinguishing among four levels of scientific evidence, especially with language only claims. This is the point-counterpoint.

What we did in this situation was we actually had consumers do what we were calling a

card sort exercise. So, we gave them four different kinds of statements. What is important to point out here, and for the rest of the discussion, is that in this particular IFIC study we did look at A level claims in this study. So, it is important to note here, and we can make some judgments based on what we found in the data about how consumers may be looking at A or unqualified claims in relationship to all these other levels.

So, in this case they were given four statements, and what they were asked to do is put them in order, one through four. One would be the strong evidence and would be the little evidence. Then, you can kind of see the language that was included in the claim statement underneath each of these cards.

So, the first one, we would have hoped people would have placed that with the actual current unqualified claim--calcium may reduce the risk of osteoporosis, let's say. Promising but not conclusive would be considered the B. C, limited and not conclusive. Then, very limited and

preliminary. So, we would have hoped that people would be able, looking at the language, critically make a judgment to place these in the correct order.

What we found is that the majority of the consumers incorrectly placed claims as to the level of scientific evidence. If you look at responses given by statement, you will see a stair-wise process kind of happening with those marked in the red box. So, if we look at the unqualified claim, about 36 percent of those folks put the A claim where it should have been, in first place, giving it a number one essentially. But then if you look at the right-hand side you see that 64 percent of consumers actually placed it in the wrong place. They didn't necessarily put it in D but they could have put it in C or B. You see the same thing happening with B, 39 percent put it in the correct place, the B place, but then 61 percent put it in the incorrect place.

So, the idea is that in giving the consumers a card sort exercise, thinking that they

would critically look at the language and then make some inference based on that language, they didn't do what we thought. A majority of them placed it incorrectly. So, 78 percent of consumers actually cannot correctly sort these four levels. Nearly a quarter got it right so 22 percent got it right.

We then asked a question, hey, do you think this was easy? Was this hard to do? You know, we were kind of trying to get at did they think this was easy. Only one-fourth of consumers felt it was easy. Out of those, one-fourth, only 32 percent of those actually got it right.

I also just want to make a statement that we did ask a battery of questions in the beginning to determine, you know, would someone would consider themselves to be what we would call more health active, someone who says, yeah, I take a really strong interest in searching out this kind of information; my family and friends actually look to me for nutrition information--those type of questions. Those health active folks, you know, we thought maybe they would be actually suited for

this kind of exercise and, by having the knowledge that they have, perhaps they would be a bit more critical about looking at the language included in these statements.

What we actually found is that they were not. So, the health active consumers were no more likely than what we would consider moderate or just very general active consumers in terms of putting these in the correct order. So, by someone thinking that they were more capable or had more information, those folks were no more able to do this exercise correctly than those who were not health active.

Now we are going to move on and say, all right, what happens if we add a report card or a graphic here? So, consumers can distinguish among four levels of scientific evidence using a report card graphic. The green line here--this is very similar to how Brenda presented here data--this is the report card graphic, again looking at that check box. What we found is that consumers can truly distinguish among four levels of scientific

evidence using a report card graphic. We would expect this in the sense that people know, for example, that A is better than B, B is better than D in grade school, and so on. So, this isn't necessarily a surprise.

When we looked at the report card text--that is when we go ahead an pull in the actual A, B or C and pull it into a statement within the claim that says FDA evaluated this claim and gave it a B rating on a scale of A to D--what we see happening here, and in this case we did test a claim, is that a two-tier approach or a two-tier system seems to be happening. While we would think that consumers read the claim and are actually thinking A, B, C and D, in fact, they actually clump or put together A and B and push down C and D. So, in this case A and B are not distinguished from each other, and C and D are not distinguished from each other. But there is a difference between these two levels, those two that I mentioned, A/B, C/D.

Now, what happens with point-counterpoint?

In these two language only formats, point-counterpoint and embedded, again, we used the current unqualified language for the A level and we did test that. But what we see here is a much weaker two-tiered system essentially emerging. So, in this case B is distinguished from C and D but C and D are not distinguished from each other. Okay? So, the two levels here are B and then the second level is C/D. Then for the embedded we found very similar to what FDA found. Really consumers did not distinguish among these levels at all.

So, what about the A claim? How is the A current unqualified language viewed, for example, within report card text or graphic? It is actually viewed as being a C level. So, if you still wanted to somehow keep a record card in terms of qualified, some kind of check box or using letter grades B, C and D, what we find is that if we keep A level language the same it will be viewed very similar to a C level claim.

So, consumers can distinguish among four levels of science using a report card graphic and

then we saw how the others fared. But then with this graphic we saw negative consequences observed in consumer perception of product safety, quality and healthfulness at some lower levels.

A lot of these slides are going to look very similar. Really what you need to know--and all of this actually is included in the executive summary. If you go back to your office, or whatever, there is a section for you to click so you can keep some of these major findings right there. But the statements at the top of these slides really do indicate where there are statistically significant differences.

What is important I think to note here, in my opinion, is that while I am listing out for you where the statistically significant differences are, in some instances it is also important to note where there were not statistically significant differences as well.

The C report card text and D report graphic in some instances conveyed less helpfulness than structure/ function and several B kinds of

claims. D report graphic and text--and you will see those denoted by the green on the graph--convey less quality than structure/function and alternative B, and I will explain what alternative B is at another time. And, D report card graphic also conveys less quality than report card text A. So, that is a nice, clear piece right there. With safety, we see that C report card text conveys less safety than some A and B claims and also the structure/function.

I would really like to look at this data again to see if we remove some of the different statements--you know, what is interesting here is that we don't see the same thing happening in every single instance, but the point is that we are seeing enough to say, you know, there is something here. In some ways, this is really impacting consumers' perceptions of these particular product attributes in a very negative way.

I will explain, and Dr. Bradbard mentioned a little bit about focus group data and while we can't make this inference for the whole U.S.

population I do think that this is something that really can drive the point home, that we asked consumers given two products, equal in all other ways but on product 1 you saw an A level claim and on product 2 you saw no claim, consumers stated that they would choose the product with the A on it.

Second scenario, two products, the same except for the statement that was on them. One product contained nothing on it, no statements of diet-disease relationship; the second product contained a statement but it also connected that D to it. They said I would pick the one with nothing on it.

Again, that was a focus group finding but it kind of just drives this point home that this kind of way or simplifying the scientific evidence can actually negatively impact consumers and actually mislead them. We saw also the same thing, that consumers are actually less likely to purchase a product with a D report card text claim than those who saw several different other kind of

higher level claims.

This is the last finding, consumers rate the scientific evidence and other attributes of a product containing an unqualified claim similar to those products containing either a structure/function statement or a dietary-guided statement.

FDA looked at this data as well, what if we take the word "may" away from the current unqualified claim, and would that have any impact? That was actually one of the questions that was being asked. We actually found that consumers did not perceive a difference here in terms of scientific evidence. I think, you know, at various focus groups we found similar things. Sometimes consumers actually like seeing the word "may" and sometimes they don't. They think that is enough of a qualifier. So, in this instance there was no difference for us when we compared consumers' responses regarding the strength of scientific evidence between claims that contained the word "may" and those that actually deleted it or removed

it.

We also compared the rating of scientific evidence for structure/function claims. In this case we actually found that consumers do, in fact, rate structure/function claims very similar to current unqualified claims whether they would include "may" or not.

So, to Dr. Ippolito's point before, does this, for example, state, as I said earlier, that current unqualified language in a report card format would really be considered a C level claim, and now we see here that there is designation between structure/function and current unqualified language. Does this beg the question should we be looking actually at unqualified claims and pushing up the language included in there just by the very fact that we may even talk about science in that claim as a change?

Now I want to move on to dietary guidance statements. We did look at different kinds of products here. Orange juice vitamin C and cancer was the relationship; yoghurt calcium and

osteoporosis; and then tuna omega-3 and heart disease. I am going to go through a little bit about what these statements were like just for the orange juice, cancer, vitamin C diet-disease relationship, but if you look at the executive summary you will see all of the different kinds of statements listed there.

The first one--this was actually an alternative to what the current dietary guidance statement is for fruits and vegetables, the current dietary guidance statement that is made in conjunction with FDA and then the National Cancer Institute. So, based on some of the earlier presentations, we wanted to look at what about a more general statement around dietary guidance? So, the alternative dietary guidance statement we tested was "eat five fruits and vegetables a day for good health." Then the current dietary guidance statement for fruits and vegetables, "diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases." So, there is a real big difference here

in that, in fact, the dietary guidance statement is actually mentioning not overall general health but talking about risk reduction for certain chronic diseases.

Then there was a question in some earlier FDA communication, what if we then also included a dietary guidance statement in the product? So, "diets rich in fruits and vegetables, including orange juice," in this case, "may reduce the risk of some types of cancer and other chronic disease?" So, we included the product here.

Then we also wanted to compare this to current unqualified claims for a similar kind of relationship. So, here is the current unqualified claim. Then we also wanted to pair the current unqualified claim with the product. So, in two instances we included product, one with the dietary guidance statement, one with the current unqualified language. We did a very similar thing then for the other two products as well.

On the left-hand side you will see a straight line. Basically, what that is letting us

know is that out of those five statements that we tested--alternative dietary guidance, the current dietary guidance, dietary guidance with product, unqualified claim, unqualified claim with mention of a product--consumers did not rate any of these different based on the scientific evidence supporting the claim. So, they were looking at them very similarly. They weren't looking at them differently.

Then, just to pull back in some of the data around current unqualified language, around "may" or no "may" and then also structure/function, we really do not see consumers being able to or wanting to distinguish among these kind of statements, dietary guidance, unqualified claims or structure/function. They are viewing them very similarly in terms of the scientific evidence.

So, this is a repeat and I will go through it quickly, but just to kind of ground us back to where we began, the claim type level perception of the product, awareness of the nutrient, in addition to a bunch of other things, actually plan a role in

consumers critically making a judgment about various kinds of claims.

Consumers have difficulty distinguishing among four levels of scientific evidence, essentially with language only claims, point-counterpoint and embedded. When we add a graphic in there, that seems to help consumers in terms of distinguishing among scientific evidence within those four levels but, unfortunately, we see some negative effects happening at lower level grades in terms of other product attributes--healthfulness, quality, safety and also purchase intent.

If we look at current unqualified language, consumers really rate the scientific evidence behind those, or that diet-disease relationship, very similarly across three kinds of statements, unqualified, structure/function and dietary guidance.

So, in summary, consumers had difficulty sorting out strength of scientific evidence associated with various claims, regardless of the

type. We found in some other kinds of research, a lot of focus group research, that perhaps consumers are really searching out some simpler language and positive language, such as we find in structure/function. Perhaps, to Dr. Ippolito's point, maybe we haven't found the right language for health claims just yet.

Then, unintended effects were observed when we tried to simplify with report cards. We saw some unintended effects. So, while it can help consumers perhaps look at science, it has some unintended effects which can actually mislead consumers about other product attributes.

Finally, of course, further research could be definitely--we could definitely use that to find out the ideal number of levels that perhaps could increase consumers' ability to distinguish. We know from our research that four levels in this instance is likely too many, but what we don't know is if three or two--what would truly be the right number of levels. Also, the terminology or language that consumers would find most helpful and

motivating in terms of making healthful choices.

So, thank you so much for your attention. I really appreciate it.

[Applause]

MS. FRASER: I want to thank Wendy and if I could get her to stay for five minutes of so, if there are any clarifying questions, please step up to one of the microphones in the aisle and state your name and affiliation. We have a little bit of time and I think we might be able to get to the next presentation before lunch and that will give us some more time in the afternoon for comments.

MR. EMORD: Hi, Jonathan Emord again. How are you?

MS. KAPSAK: Good. How are you?

MR. EMORD: From all these presentations, it occurs to me that there is sort of a pre-supposition that FDA placement of a claim in a particular category, A, B, C or D, is an appropriate supposition and that if there is a deviation from it, for example, on the part of an individual consumer that that has not been

ascertained and evaluated. In other words, if you were to ask a scientist who was well versed in the particular nutrient-disease relationship, he might well disagree or she might well disagree with the FDA's placement. How would that then affect a response? Alternatively, if someone was completely unaware of the scientific information in a particular area, they might well not have any specific regard or respect for the FDA's scientific assessment. In other words, the question is what, if anything, was done to ascertain the extent of knowledge, education and training of the participants and how that would affect their assessment of the rating system or responses to the questions?

MS. KAPSAK: I think you might have asked a similar question of the other research too, but basically we haven't cut it like that per se. The only thing we did that would get to that was that card sort exercise and, again, it is important to note that we are talking about general consumers here. So, what we did with general, broad

consumers is we did do that card sort exercise, regardless of all those knowledge things which we did look at as well to find out, for example in this case, could health active, those who we would expect to make a better, more critical judgment--maybe not at the Ph.D., but make a more critical judgment, were they able to put these in the correct order, and really what you are saying is critically evaluate, and they were not.

But, certainly, after we made them look at all these claims, we did ask them how aware were you, and we did do some awareness and also some demographics that would include obviously what you are asking in terms of education and things like that. So, we could certainly attempt to cut the research that way but, again, I think what is important is whatever happens, I mean, we are not going to be doing it just for scientists or just for highly educated people. I mean, we are going to be doing it for all Americans so in this case that is what we were looking at.

MR. EMORD: Another confounding problem

that I think may arise, and I don't know whether this was taken care of in the study, is people's preexisting opinion of the Food and Drug Administration. I mean, there is negative publicity about FDA, quite a bit of it in the last five years; hearings before Congress, and so forth, that are adverse. And, I would think that the average consumer who may be aware of that, it may affect their judgment as to whether or not when those statements say the FDA has determined this, whether that affects them. Was there any effort to ascertain what a consumer's perception is of the claim based on any preexisting bias for or against the Food and Drug Administration?

MS. KAPSAK: I have to look back at our data during the break, but we did ask consumers in focus groups a little bit about what you are saying, what their opinion was, who do they trust, and that kind of thing. Basically, what we found is that there is overwhelming trust in the FDA. In fact, they felt that FDA wouldn't allow certain kinds of claims actually to be on labels. So,

there was actually a lot of trust from the consumers in those focus groups, and I will look to see if we asked the question.

MR. EMORD: Were those focus groups inside or outside the Beltway?

MS. KAPSAK: Outside, and there were no FDA-ers in them either.

DR. MURPHY: Hi. Dennis Murphy again. First of all, I want to congratulate you for what is an extremely extensive, ambitious and productive study. I am very jealous and I want to encourage you not to lower your ambition--

MS. KAPSAK: Please don't be jealous!

[Laughter]

DR. MURPHY: Jealous of your budget. My clarification goes to these negative effects you were finding for the report card scheme, kind of spill-over effects, say, on product safety. All the comparisons you mentioned were between, across different schemes, whether report card C was lower in safety, say, than an embedded B text. Of course, we are only going to end up with one scheme

presumably. So, it seems to me that the more relevant question is did you observe these negative spill-overs within the report card scheme, particularly the graphic. Just eye-baling the graphs I couldn't see anything but I didn't have the data. My question is did you analyze that separately?

MS. KAPSAK: What we can do is we can look to see if there were significant differences within a particular scheme. I would have to go back and look myself but I think it is a great question.

DR. MURPHY: Thank you.

DR. SIMONE: I just have a quick question--

MS. FRASER: Excuse me--

DR. SIMONE: Dr. Simone.

MS. FRASER: Thank you.

DR. SIMONE: You did a great job. I want to congratulate you as well.

MS. KAPSAK: Thank you.

DR. SIMONE: You had a lot of stress doing this. Right?

MS. KAPSAK: Oh, yes.

DR. SIMONE: So, on a scale of 0-3, how much stress did you have?

[Laughter]

MS. KAPSAK: I think both of my bosses are sitting right here. Perhaps you could talk to them after this and I could get some kind of reward, or something.

[Laughter]

DR. SIMONE: You will get a reward, but give me a number on a scale of 0-3, how much stress?

MS. KAPSAK: How is my stress right now? It is zero because I am done.

[Laughter]

DR. SIMONE: Before you came here?

MS. KAPSAK: Before I came? We have given this presentation before so it is fine.

DR. SIMONE: The point I am trying to make is I think a lot of this information is very, very complicated.

MS. KAPSAK: Sure.

DR. SIMONE: I deal with cancer all the time and it is a very complicated subject and I try to simplify it all the time. So, if we can get some kind of a scale that is meaningful to people, like if I asked you the same questions, 0-3, you would probably tell me a 3 from the prior statement

or two that you made. That is easily understandable by people. I think we need something easily understood by people--

MS. FRASER: Excuse me. I know you are scheduled to speak this afternoon, if you would save those comments for then. These are really clarifying questions at this opportunity. I would appreciate it if we would stay on that side, and welcome your comments at the opportunity this afternoon.

MS. KAPSAK: And certainly there could be more research about the number of levels which may help consumers, and how that is communicated.

MS. FRASER: Well, thank you very much for that wonderful presentation.

[Applause]

If you all are in agreement, I think we could do the next presentation before lunch, which will save us some more time after lunch for comments. So, with that, as we switch over, it is my pleasure to welcome from the lovely State of West Virginia and West Virginia University Dr. Paula Fitzgerald Bone and Dr. Karen Russo France to do an overview of their research findings. We thank them very much for traveling here to join us

today.

West Virginia University Research

DR. BONE: You have no idea how exciting it is for an academic to be here with everybody. We are thrilled to be here. My colleague, Karen France, will do the final part of the presentation and I will get you started.

We thought we were starting after lunch so I was going to review what it was that we were talking about--

[Laughter]

Obviously, we are dealing with Dietary Supplement Health Education Act. We are dealing

with outcome of Pearson v. Shalala, and really looking at how do we best communicate information in the marketplace so consumers can make good decisions.

So, Karen and I got started on this because there was a change in the communication in the information environment. So, we started thinking about what is going on? What is it that consumers use, and how do they use this information that is out in the marketplace? We looked at what we called two paradigms of information decision-making, the direct effects model which seems to be how the world is operating, at least from the courts and from DSHEA, and then I will provide you with information and we will then incorporate that information into your decision-making accordingly.

Or, perhaps another paradigm that is important and comes out through the consumer behavior literature, and that is there are filters in interpreting this information in light of other things that are going on in my life. Existing

literature, clearly DSHEA and the Pearson decision left us in an environment where there is a claim, a structure/function claim and a disclaimer--the FDA has not evaluated this claim, so forth and so on. The Pearson decision left us with the health claim--the disease claim is what we were calling it during the time we wrote this paper, and then the disclaimer on the level of scientific certainty.

The evidence about disclaimers in the consumer behavior literature--often we have found that consumers may not interpret that disclaimer the way that we had intended. In fact, in some of the research today you have seen that the claim had maybe the opposite effect that we had intended. Maybe they are feeling more supportive of information because there is a disclaimer. We find that the actual information in that disclaimer is important in the health area. Telling you that there are 350 mg of sodium in a particular product may or may not have meaning. Those of you that are dietary experts, please excuse my sample if it is way off or way on. But having a lot of sodium or

55 percent of the whole amount of sodium that you may have may have more meaning. So, there are absolute disclaimers may not be as specific as specific risk or level of high, medium, low, and they have to be very carefully, very specifically worded to have the effect that we are looking for, and I think that we saw that in the FTC study where really, really, really, really this is really, really true as our highest level of claim, moving on down.

I have a quote from some of the people out at Marquette and Arkansas that are studying this particular issue, the whole disclaimers issue, not necessarily in this context. This is from Andrews, Netermeyer and Burton: The history of print advertising disclosures in curing misleading advertising impression is not good.

Another quote from one of our colleagues sitting in this room: There was an unimpressive showing of the remedy disclosures. So, that is coming out of the early work that Dennis Murphy and his colleagues have done.

So, we know kind of off the bat that we are dealing with a difficult situation in using words to clarify major statements. Just as a

review, things that we thought should or what we hoped was happening out in the marketplace, structure/function claims, informed consumers that a product supports a particular body function, though it should not lead you to believe that this product prevents, cures or treats a particular disease. That is not the intent; it is to show support of a particular function--the DSHEA disclaimer that says the FDA has not evaluated this statement, this product is not intended to treat, cure or reduce the risk of whatever.

This should ensure then that consumers understand the FDA has not evaluated the claim and should reduce the belief that the product has the ability to prevent, treat or cure disease so how we think the disclaimer should be operating in the marketplace and what that disclaimer should help do in consumers' beliefs. Disease claims may reduce the risk of kinds of claims imply a specifically

indicated relationship between that supplement and a particular disease and, in particular, should help us. We should see a different relationship between whether this product prevents a disease or not.

The scientific evidence disclaimer, dealing with various levels of emerging science that we have in the food and supplement industry, should do something about reducing their belief that this is a scientifically proven fact, and it is kind of an interesting disclaimer in our minds because most of the disclaimers that have been studied have been something along the lines of this product will be delivered within five to seven days, except if you live in Alaska and Hawaii because those are very, very far away, or something that clarifies that this is a 1.5 diamond carat measure to the 0.005 weight or something of that nature where, in the scientific evidence study, it is almost contradicting the basic claim. So, with the tomato claim that was approved--what?--last week or so, we have a claim that states "may reduce

the risk of prostate cancer," and then within the disclaimer it says, "the FDA concludes that there is very little scientific evidence supporting this claim," which is almost a contradiction in what is being stated overall. So, it is a very different type of disclaimer in our minds.

The direct effect models--consumers beliefs should be significantly affected by information on the label. If I read on the label that tomato sauce reduces the risk of prostate cancer and that the scientific evidence for this risk is little, then I should go out and operate in the marketplace knowing that that is the case. Okay, I say it or actually manufacture it; the FDA says it. The consumer then immediately takes that and moves that into his or her belief system.

However, we have seen a lot of evidence in the marketplace that that is not how consumers operate with information. In fact, we think of this as a filters model. The meaning that a consumer gets from a particular claim or disclaimer is interpreted in light of what is already in his

or her memory; what is motivating to that person; what is important to that person; and probably one of the most pervasive biases that we find in consumer behavior is a confirmatory bias. I interpret the information that you present to me to be consistent with my own beliefs. If it is consistent with my own beliefs, it is fact. It is a proven thing. If it is inconsistent, the FDA doesn't know what it is talking about. That manufacturer is just trying to sell me something. That information may be discounted based on other beliefs that I may have. We are motivated as people to maintain consistency with our beliefs. That is why it is so hard for us to incorporate information that is inconsistent because it simply can't be true and we will figure out, as consumers, a way to make it not true unless it is consistent.

We tried to identify some of these beliefs that may affect how consumer interpret a claim and the disclaimer. In the marketing literature--we tell you, this is a very good cookie. You eat the cookie and, wow, it is a very good cookie. But

well beyond that, in this line of literature if it is not just about this is a good supplement or this is a good food product, nutritional food, there are some very far-reaching beliefs that we thought could impact how you use the information that is on the product label. Government trust--do you trust the FDA? Do you trust the government to provide safe and effective products on the shelf? If you do, then what the FDA says, that is good. That is what I am going to believe. It is what I am reading as consistent. If you don't, then you are going to discount that part of the claim that you perceive as coming from the FDA because you don't trust the FDA.

Health motivation, getting at something that Wendy was talking about--how motivated are you to take preventive action to improve your health? As a short 44 year-old female, I am pretty motivated not to be a shorter 75 year-old female--

[Laughter]

Right? So, I am looking for what is going to keep me from getting shorter, getting

osteoporosis--calcium, that is it! Right? This is a good thing. I am going to incorporate that. If I am not that motivated, I may not be looking at these emerging science issues and it doesn't really matter to my own health.

Tangential attitudes--there are people who think that supplements and foods truly are the key to their health. They believe that these industries have the very best consumers' interests at heart. There are others that are going, ah, it really doesn't matter. I think one of the easiest ways to think about these specific industries--supplement industry, government trust and health motivation is a best seller right now. Most of you in this room are probably very aware of the natural cures that they won't let you know about. I am not going to have anybody do self-disclosure, but some of you are going, great! They are keeping information from you. Others are going, I can't believe they are going to allow this to be published. Right?

[Laughter]

So, there is diversity within this group on the content, the editorial content of this, and that certainly influences how we are evaluating

information in the marketplace.

Finally, if you are a supplement user you probably believe in the supplement industry as well as your behavior in using that product. So, you would be predisposed to actually evaluate that and say this good; it really will reduce my risk. And, we know that women tend to be more holistic in their evaluations. They tend to use more characteristics than men do. We know that as we age we tend to have different types of processing of information and I think that is important because, as we age, we also become more mortal and so we are using this information a little bit more. Then, the education level--those people who are more highly educated seem to have more knowledge about the area and tend to make finer differentiation in categories than those with less education.

So, to kind of look at these things--and

we are not as gifted as other people in the room; we couldn't figure out how to incorporate our label into the slides. We are pretty excited that we got slides together! We had two different supplement labels, one which is garlic, which is a well-known, well used supplement. The other is herb X. That is what we wanted to do to take into account preexisting knowledge. With herb X there would be no preexisting knowledge because they don't know what we are talking about. And, we have five different types of claim and disclaimer combinations: a structure/function only; a structure/function with DSHEA; a disease claim or a health claim only; a disease claim with a short version because there is some evidence that the longer one people just don't read and they don't incorporate it; and then the long version, the post Pearson; and then a no claim or disclaimer control for the garlic itself.

Structure/function claim: garlic maintains a healthy circulatory system. The DSHEA disclaimer you are familiar with because it is standard

throughout product. Disease claim, the consumption of garlic may reduce the risk of coronary heart disease. A short disclaimer, just with the scientific evidence; and the long disclaimer goes through the general populations versus specific populations and whole foods kinds of issues.

Dependent measures--all of this is in Journal of Consumer Affairs--what is it?--the summer edition. I am going to go through it pretty quickly and let Karen get to the results. We did structure/function beliefs. Does this maintain this particular system? We did disease-relevant beliefs. Does it reduce the risk, cure or treat this particular disease? Scientific certainty that everyone in here has spoken about; and finally one that is a little different is did the FDA actually evaluate this particular product?

So, I am going to turn it over to Karen to talk about our procedures.

DR. FRANCE: You would think that after years of doing work with Paula I would learn to do the front end of the presentations but I have ten

minutes here to discuss the results--

[Laughter]

--but that is okay, I should be able to go through it relatively quickly. Just to tell you what we did real fast, we did mall intercepts at seven different geographic locations. We had a sample to match the U.S. Census population, and then we randomly assigned subjects to see one of the different treatment labels.

We also took a number of different measures, as Paul said--trust in the government, the FDA is they wouldn't let a harmful product out there. Health motivation--I am going to protect myself from different health hazards. Trust in the industry--I believe that the supplement industry is generally providing me good information about their products. Supplement innovativeness, supplement use--we had them list the different supplements. Then, different demographic characteristics.

Importantly, I want to just mention that we had the label in full view of the respondents when they answered the questions. So, it simulated

a shopping experience. They didn't have to recall the information.

All right, real quickly just the various hypotheses that we tested, the first one look at what the impact of disease beliefs were. The disease beliefs we would expect to be lower when exposed to the structure/function claim than when exposed to the disease claim. So, we would expect the relationship between the dietary supplement and the disease to be lower when they saw the structure/function claim. We find no support for this. So, it appears that the respondents were interpreting the structure/function claim similar to the disease claim.

If the consumers would be using the DSHEA disclaimer we would expect that the presence of that disclaimer--if they are using it, we would expect that the presence of that disclaimer would lead to the belief that the FDA has not evaluated those statements. So, even with the disclaimer present we see that subjects believe that FDA has evaluated the disclaimer. So, even with the

disclaimer there, they are saying, yes, we think they are still evaluating it.

In the third hypothesis we are looking at the effectiveness of the dietary supplement. Again, we would believe disease beliefs should be lower if the DSHEA disclaimer is used. Again, we find no difference in disease beliefs with the structure/function claim only and the structure/function claim with the DSHEA disclaimer. So, again, it doesn't seem to be that subjects are using the disclaimer even though it very clearly states, again, that the product is not intended to diagnose, treat or prevent any disease--again, the same beliefs were being found.

Here we are looking at scientific certainty beliefs. Again, if they are using the post-Pearson disclaimer we should see lower scientific certainty and beliefs. Again, despite the presence of the disclaimer this is not what we are finding. So, even with the presence of the disclaimer, and sometimes a long disclaimer, consumers' beliefs regarding the scientific

certainty seem to be unaltered.

With hypothesis five we are looking at the effectiveness of the supplement and, again, disease beliefs should be lower when the scientific certainty disclaimer is present. Again, this is not going to be the case. So, when we are looking just at the direct effects model we find very little support. So, we find very little support for the use of the information on the package label impacting consumer beliefs.

Then we decided to look at the filters model and see how these various filters that we discussed are impacting consumers' perception. The first thing that we wanted to look at was this prior knowledge belief. So, when we look at prior knowledge we should see an impact of well-known supplements versus unknown supplements, so the garlic compared to herb X.

We see a non-significant interaction. For herb X there are no significant differences between structure/function believes and disease beliefs. It does not seem to be the case that prior

knowledge has some impact here.

So, let's look at these different attitudinal filters, the distal attitudinal filters. Hypothesis seven looked at trust in the government. So, what we would expect is that trust in the government should be positively related to the belief that the FDA is evaluating these claims, that they are being evaluated. If you have higher trust in the government you would believe that the government is out there protecting you and we would see a more positive attitude. So, as Paula had said, were actually discounting that disclaimer because they want to maintain consistent beliefs. We do find this to be the case, that higher levels of trust in the government relate to the belief that the FDA is evaluating that product.

Similarly, if we look at health motivation it should be positively related, again, to disease beliefs. This is what we find. So, we do find support that those distal attitudinal filters are impacting the way in which people process the package information.

If we look at the tangential attitudinal filters, we are looking at basically trust in the industry and supplement innovativeness. So, if we

see that consumers who have preexisting positive beliefs about the dietary supplement industry, those individuals should believe that the supplement is more effective than those with preexisting negative beliefs. We do find, again, that industry trust and supplement innovativeness is positively related to structure/function and disease beliefs.

We also find supplement use to be positively related to disease beliefs. And, the more they use, the more they believe this. So, they believe that the supplement is effective in reducing symptoms and that the FDA has also evaluated those claims.

With respect to the demographic filters, the only one that has a significant impact on processing of the label information is education. Those with higher levels of education seem to have lower disease belief scores, lower scientific

certainty scores. In other words, they don't believe that it is being evaluated. And, lower beliefs in the FDA evaluation. So, it seems like they may be more skeptical and maybe they are processing the label in a little more detail.

In conclusion, just to tell you the study's findings generally, we find that structure/function claims lead to equivalent beliefs as disease claims. It seems as though they are using those two claims equivalently, that they are not really making any distinction between them.

The DSHEA disclaimer did not effectively lower beliefs regarding the FDA evaluation, nor regarding product efficacy. The scientific evidence disclaimers that we used had no effect on consumer scientific certainty scores. Thus, the claims and disclaimers appear to be ineffective in reaching consumer knowledge goals that Paula had talked about.

We do see an impact of the biasing, the filters. This suggests that the package information, the information presented on the

package can be overridden by these preexisting beliefs, that people do, in fact, filter the information on the package to be consistent in some way with what their preexisting beliefs were. So, this is disturbing because those that use and, thus, are most exposed to the claims and disclaimers are the least affected by the package labels and, therefore, may use supplements that are not useful. Alternatively, those who have negative beliefs may eliminate the consideration of certain products also from their consideration set. So, it can work both ways.

There are some bounds of the research which are expounded on, thanks to our reviewers in the JCA article. We are also starting another study--we will be pretesting in a couple of weeks--that is addressing some of these issues. But, basically, the area is extremely interesting. It appears from the results of our studies and some of the other studies that the consumers, and the goal of consumer knowledge, is not been met by the current level of claims and disclaimers on the

package labels. So, thank you.

[Applause]

MS. FRASER: If we can have both of you stay, and you can either stand or sit here, whichever you prefer, and we will take a similar opportunity to ask some clarifying questions. We will push back the lunch hour a little bit so you won't lose the hour. If you have any clarifying questions, please come to one of the two microphones and state your name and affiliation and both of our guests will answer those questions.

MR. JOHNSON: Just a quick one. My name is Guy Johnson. What is JCA, and is this published?

DR. FRANCE: JCA is Journal of Consumer Affairs, and it is published in the summer 2005 edition.

MR. JOHNSON: Thank you.

MS. FRASER: Any other clarifying questions?

DR. FRANCE: That was an easy one to answer. Any more like that?

MS. FRASER: Well, with that, Dr. Schneeman's revised or corrected presentation--there are copies at the registration

table if you want to pick one of those up. Again, by my watch I have about 12:02. We will resume promptly in one hour from now, and we look forward to seeing you back here. Thank you.

[Luncheon recess.]

A F T E R N O O N P R O C E E D I N G S

MS. FRASER: Good afternoon. Thank you all for returning. It is now my pleasure to introduce our speaker, who has traveled the furthest, Dr. Neal Hooker, who is coming to us from Ohio State University. We welcome him to continue on our consumer studies research presentation. Please welcome Dr. Hooker.

[Applause]

Ohio State Research

DR. HOOKER: Thank you very much. This is really exciting for me, an academic, to be in this room and to have the excuse of presenting this, mostly to listen. So, in the spirit that this is a listening session, I am going to be doing a lot of listening as well. So, I thank you for the opportunity to present what is relatively two small studies. I think it is on point, but I am going to give you own disclaimer about the studies throughout--it is going to sound like a typical academician, and I really wanted to acknowledge my co-author, Ratapol Teratanavat, who is a former

Ph.D. student in the Department, and this work is taken from one of his dissertation pieces.

I wasn't going to put this slide in because I didn't think I was going to be the one to remind people about what we are talking about, but this is somewhat in that spirit but it is also to focus on what Pearson was kind of challenging and what opportunity it laid to provide innovative, emerging, novel information; impact people's diet quicker or in a transition stage prior to SSA information being available. So, the economist in me sort of sketches that out in a cost-benefit analysis in saying, well, if we were going to wait ten years for SSA to be there, how many people would have got a disease or more severe disease without this opportunity of qualified?

Again, that is not meant in a positive sense, you know, that is something that we have reached or have not yet reached. It is mostly meant in the spirit of Pearson in saying that the ruling was trying to create an environment that encourages industry to innovate, to do R&D, to

engage perhaps in clinical studies and invest in clinical studies to discover credible scientific information. Then the challenge becomes how do our current qualified health claims meet this goal?

Certain groups, when hearing after the Pearson ruling, the reactions we all saw as somewhat obvious--are we going to be flooded by a bunch of qualified messages, or are we just going to try and see too much information being presented to consumers? I think this, better than anything else, kind of characterizes that situation. If you think of a D claim, in addition to other marketing messages that will be on the front and/or side and/or back of a package, are we there already?

Again by a reminder, we have suggested example languages. Here is a B and a D. And, we have this hypothetical report card that many of us have taken and played around with. We have certainly done that. We have not done, as has been called for, word-smithing on the text. We have not focused our efforts so much on that. Instead, we have looked at the role of the report cards fairly

centrally.

I would also mention--and maybe this is my chance at the pulpit as the one with the funny accent--when we talk about A, B, C and D and we say that we have synergy from educational experiences, is that culturally sensitive as we have a more diverse population? I, for one, didn't get very many As going through high school or the equivalent just because our British system doesn't grade that well an academic position perhaps, but as we see an increasing immigrant population, is that a culturally sensitive representation? Is a numerical as an alternative relative representation something better?

If any of you are familiar with traffic light schemes the U.K. agency (FSA) has been playing around with, you know it is not dissimilar to the colors related to national security threat analyses. When you get to that sort of comparison, there are really very similar issues that we are trying to do. We are trying to communicate what was essentially a prior simple yes/no message, a

health claim is there or it is not there, a more continuous message. It is no longer yes or no; it is yes or no for As but then we have also included three other categories that you didn't know about before. And, that wasn't well grounded in psychology why three, why not two, why not five.

So, we have jumped that way without really understanding the consumer psychology approach to what is the optimal number of categories, or are categories around a particular letter or around a particular color good or bad.

Our literature on this is really a literature that looks at consumer use of product label information and has occasionally looked at front versus side versus an extended message on the back. They have tried to look at where people gather health or nutrition information. Although there is some diversion in this literature, essentially there is some feeling that there is an independent effect. So, I get some information from the front. Certain people maybe take the time and effort to turn to the nutrition facts and learn

a little bit more. But, also, that is not where consumers, particularly motivated consumers, stop. They also go out and collect secondary sources. They go out and ask for people's advice. So, this literature review is really focused on particular development of hypotheses that we use in our paper, but it is only tangentially related to the sort of stuff we are talking about today.

This really is the first time that all these four studies are being presented on a program in a single place. There have been two and three presented perhaps. So, luckily, I don't have to go through this, other than I have highlighted some of the methodological issues and differences that certainly impact how we compare results. There are obviously subject nature differences as well.

My own disclaimer is that the studies I am going to present use a very specific subpopulation, students, undergraduate students specifically at Ohio State. That is meant in the spirit of a disclaimer. However, there are studies that

suggest that may not be too bad of a group to use. We do not attest to translating these studies or these results into general population measures. That is not our goal. We don't, for example as the second reference would say we could, talk about willingness to pay estimates or how much more they are willing to pay a B versus a D or an A. There is literature that would support, even in our undergraduate student population, an ability to do that.

However, why I am most excited about using this population--think of the undergraduate student age. These kids have had their formative life only knowing NLEA. Okay? So, they didn't have a pre and post different expectation. That has been what it has been and the health claims authorized thereunder. They are also incredibly computer savvy. We use a methodology that uses self-based, computer-based experimental techniques. So, they are incredibly comfortable at using that technique.

Education has been argued by some to play a role in sensitivity to these type of label

messages. In other words, if you are not finding a reaction amongst a well-educated population--and, yes, these are OSU students but we hope that they are somewhat educated--

[Laughter]

--so if you are not finding in a very homogeneous population differences here, one tail of the distribution, it is a leap to say that you may not find them in the general population but all indications are that if you can't find a difference here you are not going to find a difference anywhere else.

And, it is also methodologically very convenient, very quick, very easy to not have to dip back into the same pool. So, it is a neat technique that we certainly have exploited.

I am going to give you a snapshot of two studies. The first, just sort of wanting to try and do what we have seen in some of these other studies and trying to do just a general ranking, can we see differences in consumer measures? I will interchangeably use consumers and students and

subjects. As somebody in the audience has said, well, even students have to eat and buy stuff. So, we were first just trying to look and see if we have differences. We used a control computer-based experimental design, very visually rich. It is essentially set up in a computer lab where undergraduate students can sign up for extra credit. They can come in, and most experiments take about 20-25 minutes, self-paced. They are each at their own screen. And, they get various stimulus material that is meant as filler, and then they go on to see the stimulus material, the label messages that we want them to focus on. Then we ask them a battery of questions afterwards.

We use five levels of the claims, much like IFIC study we have an A in there as well. This is somewhat of a departure, purposefully done, we use a functional food product that has dual, potentially synergistic health benefits. That is meant to raise this issue because those of you that track the functional foods industry will know that we don't just see a product that is only

claiming one health and/or one nutrient content or structure/function benefit. The vast majority of the recent introductions in functional foods have multiple, potentially synergistic, benefits. Yet, when we talk about qualified health claims, and if there are two health claims on a product, the presumption--well, I am not really sure what the presumption is. If one is an A and one is a D, does a consumer presume that both are Ds? Do we water down an A by putting on a D? Do we average out? Do we take the lesser of the two evils or the greater of the two? I think this is meant to stimulate because, for me, this is one of the most important things that needs to also be put into the discussion because the reality is that more of our products are going to have multiple of these messages.

So, we use a product that hopefully is somewhat on the students' radar screen. It is a cracker and it has soy protein and it is wheat based. This study it is relatively small, as I say 168 students. The demographics are of interest but

we don't fully exploit them but it is not our focus to exploit them. We are able to have a very visually rich--because these are computer screens, regular computer screens. We mock up a branded, fictitious product. If you can't quite see it, those are little soy beans dancing around the crackers. In this first study we had a fully controlled, without nutrient content, just a blank control. Then, we had a jointly presented but very significantly large report card.

The one thing we do differently to the other two studies that have used visuals is that we don't check; we kind of circle. That is a minor issue. But much like the IFIC study, you have to see the sheer space that is dedicated. There is no way that this would ever--if you required report cards, I cannot imagine that it would ever cover that sort of space. That is a separate study about how big is big enough.

Then, as you go through from A which, because it has this dual synergistic question, does have some language, even in the A but it is

essentially the usual text, well-known and less well-known. Here, on the A, this is fictitious so the hypothetical soluble fiber may reduce the risk of heart disease and some cancers. So, again a hypothetical alongside the traditional soy protein heart health message. And, we wanted to evaluate that.

In this particular study everybody gets the same nutrition facts message. We have done other studies where we have manipulated a nutrient content display and then also included differences between nutrient content and a health claim fully controlled with different manipulations.

Dependent measures--there is another academic discussion about whether you use one question or an average among questions. We have kind of gone with the latter. We think it is a little bit more valid. So, we don't just ask them one question about attitude. There should be a handout that lists these questions. If it wasn't made available, I will make sure that that file is made available for distribution along with the

slides.

So, we asked five questions for attitude, two for confidence and two for health benefit. Generally, the more questions you have, the more reliable that scale that you will construct will be.

Just to get you familiar with this type of presentation, you have already seen similar graphs. This is a seven-point scale. Okay? So, the higher the number the higher the attitude or other measure that we used. As we look across this fully controlled study we go from A down to a control. What are the differences here? Well, we get a statistically significant difference between D and B, but we get that same boomerang effect that we see in the IFIC study coming down from B to A. Okay? This is attitude towards the product, a fairly generic description.

Confidence in claim information--we get significance between D and A but not in between. I highlight those differences. Those are the only differences that we have. So, in the previous

slide we only see a difference between D and B and no other differences. Here we see a difference between D and A but there is no statistically significant separation between. Now, some of that is power but it is not just that. It is directional but it is not significant. Perceived health benefits--there is no difference, no statistically significant difference.

Significant multivariate effects and certain pair-wise differences. Okay? I am skipping through because some of that is just very analogous to what we see in the IFIC and the FDA studies. So, there is nothing particularly new there. What is new though is that we have in this experiment thought listings. That is where we take the step from this pure experimental technique towards focus groups that a lot of you in the audience are familiar with. But we essentially just ask them, hey, tell us what you think about the product label information after you have evaluated it. Okay?

Then we go in and categorize them into

these six topic areas, and this is completely open-ended; completely unstructured; unprompted, and they have the opportunity to give us multiple responses from each person. And we try and look to see what they are telling us. We do this for two reasons. We do it to validate the quantitative measures that we got in the first round. What do I mean by that? This is computer based. These kids click through the screens incredibly quickly and you wonder and worry if they really saw the subtle differences in the label. When they type stuff in they are spitting back at us what they have seen or perceived from that message. So, it validates that even though they took 0.8 of a second to evaluate the nutrition facts, they are able to tell us pretty precisely the sodium content. So, it is a validation exercise. But in the spirit of where we are with qualified health claims, it also allows us to explore a little bit about their thoughts, their feelings and their response.

The control subjects basically didn't have any health message to spit back at us and they

didn't. They just said something about, gee, it looks kind of nice. The product is kind of good. You know, it was great marketing response. We got a pretty effective label but, again, we didn't have advertising experts build it up but it looks glossy and nice and that is what they respond to.

When a health claim is present they tell us. They saw it and they list back, verbatim almost, what was buried fairly deeply in some of that qualifying language. However, when the information is consistent they focus on the product being healthy. This is something that Wendy stated very clearly. Pearson is trying to communicate the balance of scientific information. Subjects respond to product quality. If we are able to get statistically significant differences but for the wrong reason, is that meeting the spirit of Pearson? I leave that to the lawyers in the room. They have much better skill than I. So, if we are getting the result that Pearson required but for the wrong reason, should we worry about that?

We have kind of heard it mentioned from

focus group work. This is a little bit different from focus groups, although it is somewhat analogous, basically saying this is what they are telling us. These are, again, undergraduate students telling me, gee, why did they put a disclaimer that is a negative disclaimer? Why do they tell us about a health claim and then kind of pull it away?

So, that led us to want to play a little bit more with statistical power, want to focus in on the report card in particular because that was something that was picked out from the thought listing and the early results of study one.

So, all we do this time is just set up a smaller study, A and D, but now what we do is what psychologists would call argument quality manipulation. That is just a fancy way of saying some people got the report card and other people didn't. That is all that was different. We don't present this with a control in there, just really to get cell sizes as large as possible.

So, it is a 2 X 2, same dependent

measures, smaller population. Everybody got the same nutrition facts information. Then we let them get at it. Same product; same dual benefits but with and without a report card. I must admit the text, the disclaimer just feels floating in there without a report card. I mean, in retrospect, I would have liked to have pulled that down to have it placed more like the IFIC one, but to be really pure and look at position on a label, this is the more correct experimental design.

So, what did we find? The same sort of plots; seven-point scale. I will recite the three measures and then go into the same sort of setting of the thought listing. What do we get? We get separation of results. In other words, it is the same picture all the way through, statistically significant differences with and without a report card being present; statistically significant differences A versus D. So, at the end points we are getting everything that we want if what we wanted was just one level of qualification as opposed to three. Okay? So, we got the endpoint

of D. In other words, what that means is that all of these numbers are statistically significant. The same picture goes through with confidence; the same picture goes through with perceived health benefits.

In other words, we have significant multivariate and significant interaction effects, and the simple effects are significant. In other words, the report card being there helps people differentiate. That is not the best way of saying it because people aren't differentiating because people get to see only one of these, but on average consumers are able to sort. Again, that is much like the other studies that we have seen. The presence of report cards matters and it helps.

Again, when we go in and ask them, open-ended, your thoughts and feelings about the label information, product appeal, health benefits of the product, and the usefulness of the information is reinforced by the report card. So, if there is consistent or congruent information between the level that was circled and the health

claim being there and the report card, then they felt that that was reinforcing information. But they do spit back at us, hey, what is this report card doing? It tells me something but what does it tell me? Does it tell me about the overall health or the overall quality of a product as opposed to the level of scientific information upon which the claim was based? We don't get that spat back at us.

If they get D, they see inconsistent information and that worries them. They become skeptical and I love this first one, "I'm a little disturbed." Well, you could say that about most of our students but they are particularly disturbed because of the lack of information to back it up.

This other one, purposefully chosen, "after reading the FDA part" so, in other words, they perceive the report card as not necessarily being marketing communication but it is analogous to a nutrient facts panel, even though it is on the front. Okay? That is just some thought-listing stuff but I think that sort of thing needs to be

explored a little bit further about the perceived domain of a report card, or whatever cue may go on there, and the actual claim which may or may not be crafted for marketing communication reasons. And, they don't believe the information when seeing a D. So, it is skepticism, yet, FDA gives it a D rating. In other words, why tell us if you are going to pull it away?

I am not telling food industry people in the audience anything new when many have shared with me that none of them would like to market something with a D anyway. Certainly the large firms may not want to go into this for precisely these reasons, but if it was a C or a B they may be willing to try. Again, why have three levels if one level will never be used, at least by the majority of the industry? On a parenthetic note, that may be the answer you get from large industry players; it may not be the answer you get from very small agribusinesses with a novel functional food product. They may be willing to take the risk that despite all the evidence that seems to suggest that

it is a weaker attitudinal measure than even a control.

So, just to clarify, D gets differentiated. Visual aid really help consumers distinguish claim levels. Obviously, the academic is going to say we need more research. My two pitches are similar to the FTC position that a more distinct disclaimer that is a lot of work--and it doesn't just have to be focus group work; it could either be survey work or, my argument would be this sort of experimental technique is ripe for fairly rapid exploration of different wording constructs. You can try something and get a response fairly quickly either in this particular population or, if you take this same technique and put it in a more general population group, the same process can be achieved.

Then, I do want to restate that dual or synergistic health benefits, if we are seeing products released with multiple health benefits that may have very different marketing segmentation issues, in other words, we are going to have an

osteoporosis female-oriented functional characteristic and a male-oriented characteristic that may come from a different bioactive compound and, yet, it is in that same food product, and if there are different levels of qualification that are attached to each, what does the consumer receive from that? How do we kind of manage that? Do we have to put two report cards on? Do we have to put a report card on for each functional characteristic? Then we go perhaps quickly towards, well, structure/function may be a better way to deal with that.

So, with that in mind and wanting to listen now to the rest of what happens in the afternoon, my e-mail address--again, apologies, if you haven't got copies of the slides, I will make sure that this updated set is made available, along with a handout that has all the numbers. You know, I quickly presented figures but I have a handout that kind of gives the quantitative results. I would be very interested in follow-up with anybody if you have any other questions. Thank you.

[Applause]

MS. FRASER: Thank you, Dr. Hooker. As before, we will have an opportunity for some

clarifying questions. If you have any of that nature, please step up to one of the two microphone and state your name and affiliation and ask your question. Thank you.

MS. KAPSAK: I don't have a question. Is this on? MS. FRASER: It is on, and just for the transcript if you would say your name?

MS. KAPSAK: [Microphone not on; inaudible]--two claims looking at the individually. One was an A level claim, the other was a C level claim. And, there was some statistically significant difference between the rating of the scientific evidence. [inaudible]--on the report card, one report card; two checks, one for C [inaudible]--

MS. FRASER: Is that mike on? They are telling me in the booth that it is not.

MS. KAPSAK: Oh, I thought you said it was. It says it is.

MS. FRASER: It keeps going in and out.

DR. HOOKER: I think it was difficult to communicate two check marks.

MS. KAPSAK: And the scientific evidence when we put [microphone off; inaudible].

DR. HOOKER: But it went down to the

bottom? It was more like a C or was it averaging?

MS. FRASER: Wendy, come use one of these.

MS. KAPSAK: Basically, what we did was we looked at them individually. Okay? So, when we did that, A and C, there was a statistically significant difference when they rated the scientific evidence, and that was using report card graphic. When we put them together on the same report card, so a dual claim situation, instead of there being a statistically significant difference between the two ratings, in fact, there ended up being no statistical significant difference. So, what was once--this wasn't the exact numbers but let's say a 6 for an A on a 7-point scale and, say, a 3 for A/C is that they both ended up becoming 4.

DR. HOOKER: That is my expectation as you

go towards the bottom. That confounds--you are watering down your A. You know, the C one is going to be more the more novel message and when you are getting a consumer's first take on this, this is something new that wasn't on this particular product or this product wasn't particularly available before, then it is a recency issue. They are going to focus on the new thing and they are going to pull things down to that level. You know, from a marketing perspective, do you then, if you have this new thing that you want to put into your product that already has a health claim, do you market it as a different new category? Do you market it as a different new product? Do you not try and grow out your category? There are some really fascinating marketing issues in that.

MS. FRASER: Any other clarifying questions? I have a question for the folks in the control booth. Do we have a replacement microphone for here? One minute, I am told. Well, thank you very much, Dr. Hooker.

[Applause]

We now have come to the session where FDA provides an opportunity for many of you to provide comments to a panel of our FDA researchers. Our

panelists are all from the Division of Social Sciences within CFSAN's Office of regulations and Policy and are as follows, and I will ask them to come forward as I call their names: Dr. Richard Williams, Jr., who is the Associate Director for Social Sciences. In addition to the consumer studies staff, he also has the economists under his purview. Dr. Steve Bradbard, whom you met this morning, team leader for the consumer studies staff; Dr. Brenda Derby, statistician on the consumer studies team; and Dr. Alan Levy, who was the co-investigator with Dr. Derby on the FDA study, senior scientist on the consumer studies team.

I know a number of you came in after my initial remarks this morning. For those of you who were here for that, you can kind of zone out for a little bit. But as I indicated this morning, this is a consumer research public meeting.

Accordingly, we ask that your comments focus primarily on recommendations for additional consumer research in the area of health claims. We are especially interested in hearing at this time your views regarding other schemes or signals that may effectively communicate to consumers the level of scientific support for health claims, without leading consumers to make erroneous inferences about the claimed substance-disease relationship and/or other product characteristics.

We also are interested in hearing about alternative research methods that can empirically assess the effect of health impact on consumers' perceptions and behaviors. Again, this meeting is focused on research that will assist FDA policy makers, and during this portion of the meeting my four panelists will be in a listening mode. None of us is here to speak to the policies regarding health claims that may result from this research at this time. We will begin with the 20 speakers who requested an opportunity to speak. There actually were 21 but one speaker indicated that he had to

leave. These are speakers who provided the request to speak by November 10, along with the information we provided or requested in the Federal Register notice.

I will ask each speaker to limit your comments to a maximum of five minutes, and I will be monitoring the time to ensure that we can provide an opportunity for as many people as possible to comment. If you are still speaking when I signal to you that your time has elapsed, I ask that you cease speaking within 15 or 20 seconds to allow the next speaker a similar opportunity to provide comment to FDA. If we still have time after the speakers who requested an opportunity to speak in advance have made their presentations, and I think we should since I think we are about half an hour ahead of schedule, we will offer others in attendance an opportunity to provide comments, subject to a time limitation that may be shorter depending on the number of speakers. This will be kind of high tech and kind of low tech. I do have a timer. That is the mini high tech part. I have

the low tech part, the two-minute warning but please stop within 15 to 20 seconds warning. It is really not meant in any way to be rude to anyone but really to provide everyone an equal opportunity to speak.

With that, I invite our first speaker to come forward, Mr. Bruce Silverglade, the Director of Legal Affairs at the Center for Science in the Public Interest. I also ask the next speaker to come to the aisle so that he can be ready to begin immediately upon the conclusion of Mr. Silverglade's comments so we can maximize our time. Similarly, for each speaker following, please come forward as the speaker before you begins. Mr. Silverglade?

Comments outcome Panel Regarding Other Pending or Suggested Consumer Studies Research

MR. SILVERGLADE: Thank you very much. It is wonderful to see so many people here after working on this issue for 20 years. The interest never seems to go away and it seems to be a very dynamic field and an ever-changing field.

We have heard what the research says, and I think now the question is what are the implications for the FDA. While I have certainly

heard the instruction to keep away from policy, I think there are some threshold questions that we must address and I would like to make the following statement on behalf of the American College of Preventive Medicine, the American Dietetic Association, the National Consumers League, AARP and the Consumer Federation of America:

The results of consumer research conducted by both the Food and Drug Administration and the International Food Information Council indicate that disclaimers do not cure deception created by claims based on emerging science. Given the inadequacy of the disclaimers that have been used so far, FDA should rescind its prior authorizations of qualified health claims and refrain from further authorizations. The food industry has argued that FDA must allow health claims with disclaimers, citing the Pearson case. However, the court stated that under the First Amendment FDA could prohibit

claims if it had, quote, empirical evidence that disclaimers would bewilder consumers and fail to correct for deceptiveness, unquote.

FDA now has this evidence, as well as corroborating evidence from IFIC. It demonstrates that disclaimers do not cure the deception created by preliminary health claims. Thus, FDA should no longer authorize qualified health claims.

In passing the NLEA Congress was well aware of First Amendment concerns. Based on extensive hearings on abuses in food labeling at the time, Congress concluded that unless claims met the significant scientific agreement standard consumers would be misled. FDA's own research now underscores the appropriateness of Congress' original approach to regulating health claims for foods. Therefore, FDA should rescind its approval of all qualified health claims for foods and impose a moratorium on the approval of additional qualified claims that do not meet the standards of the NLEA. Thank you.

MS. FRASER: Thank you, Mr. Silverglade.

Our next speaker is Robert Earl, Senior Director for Nutrition Policy at the Food Products Association.

MR. EARL: Thank you, Leslye, and thank FDA for this public meeting today, and also all of the researchers who have contributed to this morning's discussion about consumer understanding of claims research.

The research results that we have heard about this morning and early this afternoon illustrate that the consumers both do and don't understand claims about diet-disease relationships and the uncertainty of scientific evidence portrayed in labeling and advertising. These research data illuminate that there is much room for improvement in exploring language options to best promote consumer understands of claims. It is clear that there are problems with current claims language prescribed by the agency and with rater report card schemes.

At present, perhaps too much emphasis is being placed on precision articulation on level of

science versus evaluation of consumers' understanding of claims language and ability to affect decision-making. No discussion of health claims in food labeling, both those SSA claims as well as qualified, can be considered outside the First Amendment framework that defines government's role in regulating commercial speech.

Particularly relevant is the First Amendment standard defining the nature and amount of evidence the government must have before it can restrict freedom of expression. Under the First Amendment, to justify a restriction the government must have evidence that a specific claim in question results in genuine harm to consumers and that the particular restriction will alleviate the harm to a material degree. This is a case-specific standard and the burden of proof cannot be satisfied by evidence from hypothetical claims testing conditions.

We agree that a wide variety of consumer research can help inform constructive directions for public policy. But, at the same time, general

background research cannot satisfy the evidentiary standards government must satisfy to impose restrictions. This high bar protects free speech and encourages a positive shift away from an undue focus on banning health claim expressions, and toward regulatory strategies that are effective in nourishing health claim expressions that benefit public health.

Claims can be effective in developing awareness or educating consumers. FPA suggests that information messages also should inspire and motivate the adoption of healthy food consumption practices under real-world conditions. Based on the expertise and experience of FPA members with consumer and food marketing research, greater freedom and flexibility in the expression of health claims will help produce information to drive more positive outcomes for public health.

Flexibility to make claims has been an FPA policy goal for quite some time. Most notably, we refer to this Association's 1994 petition to FDA requesting flexibility in claims. These are public

health benefits from flexibility to make truthful and non-misleading nutrition and health claims about foods, and this could occur without a compelled, rigid and narrow set of prescribed messages. The flexibility of the FTC's competent and reliable scientific evidence standard has much merit to allow FDA to concentrate efforts on developing guidance and best practices concerning claim substantiation principles, evaluation of evidence and message comprehension. Recent decisions of the agency more closely approach this model, but still lack some important flexibility.

Future consumer research needs to focus on advancing knowledge about consumers and their understanding, use and application of claims. Research should focus on message elements that work to improve public health while encouraging free flow of truthful and not misleading information to consumers. Advancing the research base may require experimentation and more creative approaches to language in the structure of both claims with significant scientific agreement and qualification.

Further, as with nutrition labeling reform, we recommend that the agency improve coordination of research projects related to

claims. A piecemeal or fragmented approach will not serve government, the public or the industry. We also recommend full transparency and opportunity for input into research protocols for consumer research projects.

In summary, the Food Products Association firmly believes in the value of health claims and qualified health claims to provide important consumer information about foods, nutrients and reduced risk of disease. Claims information must both motivate consumers towards actionable public health goals and present science in the proper context. This should be done in a non-restrictive environment that focuses on review of the evidence and freedom to craft meaningful messages for consumer benefit. We will follow up these comments with written comments submitted to the docket in the future, under the guidelines expressed in the Federal Register. Thank you for the opportunity to

present our views to you today.

MS. FRASER: Thank you, Mr. Earl. He noted a comment, all of the comments--we do ask the speakers to provide them directly to the dockets as well. Anyone who either does not speak today or is not able to speak today or doesn't want to speak today, we also encourage you to provide comments to the docket. We are relying both on the written comments in the docket as well as the comments we receive here verbally and in the transcript, and the transcript will also end up in our docket.

Our next speaker is Dr. Charles B. Simone, Director of the Simone Protective Cancer Center. Dr. Simone?

DR. SIMONE: Thank you very much. I am a medical oncologist and a radiation oncologist, and we know that two of every five people here will develop cancer, and two of every five of us will develop heart disease. Many risk factors account for it, including smoking and alcohol, etc., but nutrition seems to be most important. The National Academy of Sciences addresses this and says that 60

percent of all women's cancers are related to nutrition and 40 percent of all men's cancers are related to nutrition.

So, we have control. Only about five to seven percent of all cancers and heart disease are related to genetics. We have control to prevent disease, but we can only do this if we can educate people about proper lifestyle and the use of vitamins and minerals.

About 50 percent of all people in the country, surveyed by a federally sponsored study, NHANES III report, shows that educated or not, rich or poor, they have at least one of two marginal deficiencies of vitamins and minerals. In addition, we know that the USDA published a study last year and showed that vitamin and mineral content of foods, specifically fruits and vegetables, are down anywhere from 14-400 percent compared to 1975. So, our food supply is not what it used to be.

In addition, if you are a member of a group like drinking three glasses of alcohol per

week, you will have known deficiencies right off the bat. Birth control pills, elderly people, these have known deficiencies based on federally sponsored studies. In fact, hundreds of studies involving hundreds of thousands of people now show that we can prevent disease based on the addition of antioxidants, B vitamins, calcium, omega-3 fatty acids and other nutrients. So, we have lots of information but we are not permitted to impart this vital information to our patients.

One major study that was done by our National Cancer Institute, in China, involved the use of 30,000 people randomized, in China, and all they did was take three antioxidants and gave them to people over a five-year period of time, randomized, and showed that after five years they decreased the mortality by nine percent. Cancers were decreased by 13 percent and death by stroke by 40 percent. That is just with the addition of three antioxidants in rather low doses. So, antioxidant use, in addition to prior lifestyle, can actually dramatically affect an outcome.

We know that the Federal Trade Commission censors health information by prohibiting health benefit claims when not supported by near

conclusive proof. As we talked about this morning from two representatives, both from the FDA and the FTC, they also deal with probabilities in studies--look at studies and look at probabilities. We have to do the same thing as physician scientists. When I look at a study I say, well gee, that p value, that statistically significant value is real and so I am going to give that information to our patient. No science at all is conclusive with 100 percent certainty. We must be able to allow this information to flow freely to people.

In 1982 President Reagan's administration said the following: This new strategy of using vitamins holds promise for reducing the incidence of cancer more successfully than an attempt to move from the environment all substances which may initiate a cancer process.

Then, in 1995 the U.S. National Cancer

Institute said this: The field of chemoprevention is now considered to be an extremely promising approach to prevention of invasive cancer. We have the information. We must impart this information to our patients. We can prevent cancer; we can prevent heart disease. We have to stop the censorship from the FDA. Thank you very much for the opportunity.

[Applause]

MS. FRASER: Thank you, Dr. Simone. Our next speaker, and hopefully I won't botch your name too much but correct me, is Michael Scuicco. He is with ITV Direct Inc., Direct Marketing Concepts, Inc., and please say your name properly for the record. Thank you and welcome.

MR. SCUICCO: Thank you very much. It is very difficult to pronounce my name; I actually have difficulty myself. Hopefully, my father is not here listening.

Good afternoon. My name is Mike Scuicco. I am an attorney in Massachusetts and I am here as a member of a coalition to stop FDA and FTC

censorship. In 1998, it took a law suit by concerned citizens and companies to force this agency to recognize the health benefits of certain dietary supplements and to stop this agency from violating free speech rights protected by the First Amendment.

That case, Pearson versus Shalala, mandated this agency to allow marketers to make a health claim about omega-3 fatty acids and other dietary supplements and ruled that the FDA's policy of denying health claims violated the First Amendment. Since that time this agency has ignored that decision, has ignored a directive by the Office of Management and Budget, has ignored the overwhelming scientific evidence and continues to violate the First Amendment of the United States Constitution.

The current qualified health claim for omega-3 fatty acids is too long, too negative, and accompanied with a disclaimer that does not effectively convey the benefits of omega-3 fatty acids. We now know that over 300,000 people die

every year from sudden death heart attacks. We also know that this number could be cut in half if the American public was aware of the health benefits of omega-3 fatty acids.

This agency owes the American public an explanation of why it continues to restrain speech rather than promote speech about the health benefits of dietary supplements such as omega-3 fatty acids. This agency has spent most of its time trying to find ways to prevent health claims rather than respect precedent, the Constitution and the public health.

The FDA, an agency commissioned with the task of fostering health, is actually causing more harm to Americans by not allowing simple and concise health claims made about dietary supplements such as omega-3 fatty acids. This agency should embrace the overwhelming scientific evidence about omega-3 fatty acids and their benefits and help disseminate information rather than suppress and censor it.

We have before us several surveys. I

commend the FDA for attempting to determine the best way to provide information, although it appears that the FDA believes the American public cannot make up its own mind. In fact, the surveys revealed diversity in public opinion about the nutrient-disease claims. Our First Amendment fosters diversity of opinion, protects it and disarms the FDA of the power to restrict, block or prevent it.

In closing, this agency should promulgate a policy embracing health benefits of dietary supplements such as omega-3 fatty acids and work with the American public, the media and the supplement community to disseminate as much information as possible. Consumers and companies should not have to sue the Food and Drug Administration over and over again in order to be able to inform the public about the effect of nutrients on disease.

If this agency continues to restrain speech and censor claims of health benefits of foods and dietary supplements, it will continue to

cause more harm than good. The American public effectively loses its right to free speech and its health. No one but the drug companies benefits from this type of censorship. Thank you for your time.

[Applause]

MS. FRASER: Thank you for your comments. Our next speaker is Mr. Jonathan Emord, President of Emord and Associates.

MR. EMORD: Diversity of opinion on the meaning and worth of health claims is to be expected, and is protected by our First Amendment. The fact that these studies show diversity of opinion should come as no surprise to us. Diversity of opinion as to the meaning of health claims is commonplace, as it is for any other statement of opinions. A health claim is predicated on information, as we have heard from others, that is never-ever scientifically provable to a conclusive degree, except perhaps in the extraordinary circumstance.

So, just as in the scientific community

there is diversity opinion, so there is in the public and these studies confirm that. That will not change regardless of how the Food and Drug Administration attempts to categorize the evidence. It is because each of us comes into the world with different predispositions and notions and understandings of science, and we develop these through our lives and we have differing opinions, and that is protected by our First Amendment.

The First Amendment precedent in Miami Herald Publishing Company versus Tornio prohibits the government from censoring or restricting speech on the basis that the public fails to receive a message that the government wishes for it. There is no orthodoxy in speech under our First Amendment. The government may not establish an orthodoxy on speech. It cannot insist that everyone regard an A claim as an A claim, or a B claim as a B claim. The information is all important. The categorization of the information, if it is used in an effort to create an orthodox opinion, violates the First Amendment.

Under the First Amendment, a truthful claim may not be suppressed or restricted on the basis that the public misapprehends it. Scientific

speech is complicated. This speech is nothing more than scientific speech reduced to a sentence. Is it any wonder then that we have a diversity of opinion? Complex speech invites diversity of opinion, but diversity of opinion is no justification for suppression of information. In fact, it is a justification for allowing more of it.

So, what are some options for this agency as it continues to try to ascertain what it means to communicate a health claim and what health claims mean? Well, the First Amendment rule in Pearson versus Shalala is disclosure over suppression. Disclosure is the central characteristic of our First Amendment and a right that we all have. We have a right to receive information. When our government stands in the way of the receipt of that information it serves as a barrier to truth. Because science is evolutionary,

truth only comes to the fore with full, free and open debate.

So, what do these studies tell FDA in light of the constitutional restrictions on agency power? They tell FDA that the solution to the problem is not playing with the manner in which a claim is communicated but getting the information out; opening the doors to the information. They tell FDA that the solution of the problem is dissemination of more information about the nutrient-disease relationship. We cannot expect the consumer to be fully informed by any single health claim, nor can we expect that any single health claim will have the same meaning today as it does two years or ten years from now to the consumer. Science is evolutionary. Public understanding of it is evolutionary. Public opinion of it will change.

We cannot expect the consumer to be fully informed by a single health claim. We can never expect the consumer to subscribe to the FDA's own prescription of what the science means, nor should

we. And, to raise public awareness we have to take certain steps to eliminate the restrictions on public speech, and this will fulfill the objective of ensuring that the public has adequate information to form its own opinion.

We have to allow companies to disseminate the actual scientific studies upon which these claims are based. The government should be in the business of sponsoring and fostering open public debate about this. Scientists should be invited to debate the issues and the matter should be communicated to the media and the public generally. We should encourage companies that use the claims to include in the labeling links to posted web sites, perhaps sponsored by the government, that include all of the scientific information. The public has a right to all of the information. The government should not assume the public is ignorant and cannot comprehend it. Our First Amendment depends upon access to information. Instead of interpreting this data as a justification for suppression, we should realize that it invites FDA

to remove further barriers to truth; to foster the truth-seeking process by giving the public full access to information. Thank you.

[Applause]

MS. FRASER: Thank you, Mr. Emord. Our next speaker is Ed Jarrin, Executive Director of MLM Industry Association. Mr. Jarrin?

PARTICIPANT: I don't think he is here. I believe he had to leave.

MS. FRASER: Then we will move to Mr. Steve Wallach, General Manager of American Longevity. Welcome, Mr. Wallach.

MR. WALLACH: Has everybody enjoyed the day so far? Pretty interesting, to say the least. My name is Steve Wallach. I am the General Manager of American Longevity. Thank you for allowing me to speak.

I am well aware of the health claim petition process. American Longevity has filed three health claim petitions so I am well aware of the process. I deal with consumers on a daily basis.

Let's see, I don't have a prepared speech because I wasn't sure exactly how this would go so I just jotted down some points. During the FDA

presentation from earlier today and three of the four health claims that they discussed, one for selenium, one for lycopene and one for essential fatty acids, American Longevity had submitted to the FDA. The health claim petition process is extremely important to the consumer, as we have heard just recently, just today and just this afternoon.

The information is imperative to get to the consumer. How we do that is important but it is also most important to get that information to the consumer, as we heard Dr. Simone talk about and the gentleman that nobody can pronounce his last name--sorry. It is incredibly important information to get to the consumer, as we heard Mr. Emord talk about. Not only is it covered under our First Amendment rights but it is also important for the consumer to get this information, this life-saving information as we heard Dr. Hooker talk

about earlier today. Do we wait for the emerging science to become SSA science? That would be wrong, to throw it back to the Dark Ages to completely suppress it would be just foolish.

We were asked to talk about potential additional schemes, as it was put. One comment I would have is that I deal, in my job, with governmental agencies from around the world. I deal with governmental agencies from Canada, from Australia, from Singapore, from Japan, and the system for getting health information is quite different for getting it out to the consumers. The Therapeutic Goods Administration, the TGA of Australia, has predetermined health claim information for therapeutic goods. They don't have a dietary supplement category. They either have foods or they have therapeutic goods. Our dietary supplements would fall under the therapeutic goods scheme most of the time. If it has vitamins and minerals added, it would be a therapeutic good.

For instance, glucosamine claims that were submitted to the FDA under the health claim

petition process just recently were completely denied. In Australia we are allowed to make health claim treatment information available on the label actually for glucosamine. We are able to use the A word on the labels. Here, in the United States, we are not. So, when it comes to health claim type of information, that information is available, authorized by the TGA in a predetermined fashion.

Health Canada is the same way. That information is available from the beginning of designing a product. If your product has nutrient X, Y or Z you are able to make S, Y or Z statements associated with that that are predetermined by Health Canada and the TGA, the Therapeutic Goods Administration in Australia. The TGA and Health Canada are extremely conservative in my view. They are very protective of their peoples but, at the same time, they make this information available. They are receptive to it. For a few hundred dollars and a few weeks of product submissions, you are able to make these health claims.

I can tell you that for the lycopene claim

that was not approved, that was just denied, the FDA took two years to review. If there was inadequate science to make a claim based on emerging science, why did it take two years for that claim to be reviewed and then ultimately denied? Thank you.

[Applause]

MS. FRASER: Thank you, Mr. Wallach. We will go down through the tenth speaker and then take our 15-minute break, and then come back and resume with our speakers. Our next speaker is Dr. Julian Whitaker, Director of the Whitaker Wellness Institute. Is he present?

[No response]

Next is Mr. Andrew Shao, Vice President of CRN, Council for Responsible Nutrition. Mr. Shao is Vice President of Scientific and Regulatory Affairs at the Council for Responsible Nutrition. Welcome.

MR. SHAO: Thank you for giving me this opportunity to speak. I didn't prepare a speech either but I do want to make a couple of important

points. The first is that I think we all need to be patient and persistent, FDA, industry, academia. This is an evolving process. Science is an evolving process. There is never a final word so we need to be patient and persistent.

Despite what we have seen here today with the research results looking a little bit sketchy, we still believe that qualified health claims are important. They are important for consumers to help them make informed choices but, equally as important, they provide incentives to the industry to do research, good research, which some may argue is also lacking.

My second point is that the marketers out there know that influencing perceptions and behaviors of consumers is also a long-term, somewhat evolving educational process and may require multiple exposures of qualified health claim language to them to influence proper perception and behavior. So, one thing I would suggest to the agency in doing future research is to see what the effect is of multiple exposures of

the language. It seems to me that the research we have seen here today was really single exposure. What do you think of this right now? If folks maybe were exposed multiple times, had time to think about it, how would that influence their perception? How would that influence their behavior?

The final point I would like to make--and I think we talked about it a little bit earlier this morning--is looking more at the SSA claims and the language there. Perhaps strengthening the language around the SSA claim may help consumers better differentiate between SSA claims and qualified health claims, and maybe the different levels of qualified health claims.

An example could be one of the current SSA claims is that calcium helps reduce the risk of osteoporosis, or may reduce the risk of osteoporosis. What about changing this to strong and conclusive evidence indicates that calcium reduces the risk of osteoporosis, perhaps testing that against some of the more qualified language?

These adjustments in the SSA language may help consumers to differentiate between the relative weight of scientific evidence between them and the other levels of qualified claims. Thank you.

[Applause]

MS. FRASER: Thank you, Mr. Shao. Our next speaker is Mr. Nick Catran-Whitney, CEO of the NWM Entertainment Group. Is he present? No? Is Dr. Janie Meier here? Or, shall we just take our break? Take a break? Okay. It is 2:10. We will see you at 2:25. Thank you.

[Brief recess]

MS. FRASER: We will get started again in about two minutes, if you want to start moving back towards your seats. Our next speaker is Dr. Janie Meier, Vice President of Invision Group. Welcome, Dr. Meier.

DR. MEIER: Thank you and good afternoon. I happy to be here after the break, now that you are happy and energized and ready for the rest of the afternoon session.

I am involved in holistic health education

for the Invision Group in Los Angeles, California. My company is a member of a coalition of 57 companies in the nutritional industry. Some of us are marketers of nutrition, manufacturers of nutrition or in health services and products. These 57 companies reach over half of the American population and we have spent the entire first part of the week in Washington, D.C. meeting with over 25 congressmen and senatorial offices to introduce and support the Bill that was introduced in the House on November 9, called the Health Freedom Protection Act. It is HR 42-82, if any of you would like to look it up and join our coalition in support of health freedom protection.

I am here to also speak about the halting of the FTC censorship about nutritional information, specifically as it relates to the nutrient-disease association. If you would like to raise your hand, feel free. How many of you take food supplements, your vitamins, minerals, nutritional supplements? We take those with the belief that those supplements have benefit to us.

That belief is backed by more and more preponderance of scientific evidence, much of which is either ignored or suppressed by the FDA and its bother or sister agency, the FTC.

We find that there has been repeated need, as Emord & Associates has explained, to sue the FDA on First Amendment rights, freedom of commercial speech, that those of us in the nutritional industry no longer have to be stepping over legal boundaries to speak publicly, to address a patient one-on-one, or merely to tell our next-door neighbor about nutrient information that, in some cases, the government's own studies support but, because we are attached to a product sale, we are prevented from doing that. As soon as we do give out nutritional information, our food supplement product crosses over this line into an unapproved drug and it is all based on semantics.

Someone said here earlier that words are not a very good method to communicate the results of so much analysis and, yet, words are all we have to communicate. Words backed by passion, however, can

be very powerful on any side of a debate. Science, in and of itself, is inconclusive. Dr. Derby, this morning, stated herself that near conclusive evidence rarely exists and 100 percent conclusive evidence does not exist. Yet we, in the nutritional industry, are bound to produce near conclusive evidence of a disease-nutrient association to be able to make claims of this nature.

There have been some claims allowed now that "may help prevent," "may assist in," "may support in." We are forced to use very ambiguous language when, based on years and accumulation of scientific research and the emerging research in the marketplace, we have not heard anything in all of this analysis today--and those of us involved in commerce call this paralysis of analysis--that we can analyze things until they are turned into what we got to today, that there is no conclusive evidence in any of these analyses. What we have seen and heard is a healthy difference of opinion. But when that difference of opinion affects our

health decisions, those of us in the nutritional industry are shackled because we cannot legally share that information.

One of my favorite examples that we have shared on Capitol Hill all week long is that if you were a producer of prune juice and you wanted to state on your label that prune juice relieves chronic constipation, you are in federal violation. You could go to jail and have all your prune juice confiscated for doing that. Yet, government ignores historical and anecdotal data that we can date back 5,000 years into ayurvedic medicine, 3,000 years into Chinese medicine, all the old wives' tales that we have heard our entire lives that prune juice is good for constipation and, yet, we cannot market prune juice with that statement because of government semantic argument.

My favorite topic is women's health. That is what I specialize in and I am an American business woman who now does business in Canada. I have a television show on the air in Canada about women's health. As one of the previous speakers

stated, in Canada and in Australia there is certainly government oversight and government regulatory agencies that take, in a very timely manner, consideration of your product, analysis of your product, the research of your product and then allow you to disseminate the proper information. So, I am on public television in Canada every month talking about women's health, especially as it relates to HRT.

In my last 20 seconds all I want to do is encourage you to go to stopfdacensorship.org, take a look at our information. Please join our coalition and support HR 42-82 on the Hill now. Thank you very much.

[Applause]

MS. FRASER: Thank you, Dr. Meier, for your comments. I might also encourage you to put those in the docket so that we do have the full text of the remaining comments you wanted to make. Our next speaker--I am sorry, I should have given a heads up to Mr. Quinn. Our next speaker is not here. He had to leave. So, Mark Quinn with Basic

Research is our next speaker. Welcome.

MR. QUINN: Thank you. As the title of my remarks today, I would like to borrow a line from one of my favorite movies. That line is the problem is choice. If consumers are to have any meaningful choice about the products that they purchase they must have access to the information which will allow them to make that choice, not filtered or restricted information.

We are concerned--I work for companies in the State of Utah who are in the dietary supplement and cosmetics industries, and we are concerned about the conclusions that may be drawn from the consumer studies that we have been hearing about today, and the potential actions that FDA may take as a result of these conclusions. Specifically, we are concerned about the conclusion that consumers do not understand the strength of science disclaimers, and we believe that it would be wrong to use this conclusion to further restrict the use of health claims in the marketplace.

The studies we have been hearing about do

not, in fact, show that consumers are confused. They merely show that consumers have a different opinion from the government's opinion about the disclaimers that are being used on these products. Government doesn't like difference of opinion. The government wants you to believe their opinion so they interpret difference of opinion as confusion when, in fact, confusion doesn't exist. The fact that consumer surveyed at a shopping mall do not uniformly understand the strength of science disclaimers utilized by the FDA is not surprising. But the remedy to that problem is not to give consumers less information. The remedy is to give them all of the information and allow health claims on products to be the beginning of a healthy debate in the marketplace about the relative merits of these claims made by product suppliers.

When consumers understand where they can go to find out more information about a health claim on a product, they can access all the information available and can make informed decisions about which products to use and the

effects that such products may have on their health. Product suppliers cannot currently make available to consumers information about the scientific evidence supporting a health claim or even tell consumers where they can go to get this information, even when the information comes from the government's own studies.

The result is that much of the scientific literature about particular products is not getting to consumers and they cannot make informed choices. Our government should not be in the business of trying to rate the level of science supporting a health claim. Government attempts to do this will inevitably result in differences of opinion and, as the government interprets it, consumer confusion because even scientists, let alone consumers, may and often do disagree about the relative merits of particular scientific studies. FDA should not be concerned about such disagreement. It is a healthy and normal part of ongoing debate in the marketplace and it should not be FDA's role to attempt to insert itself between the consumer and

the scientific information.

The role of FDA should be to simply provide access to all the scientific information and let consumers decide for themselves what relative strength to accord the scientific evidence in support of a health claim. It is important for the FDA to restrict or prohibit claims that have no support at all in the scientific literature, but it is detrimental to consumer choice for the FDA to get involved in crediting or discrediting scientific evidence that exists in support of health claims because there is no way to fairly and accurately do this. Once scientific evidence exists in support of a health claim, FDA should simply get out of the way and allow consumers to make their own decision about it based on all available information.

The freedom to make our own choices is part of our birth right as American citizens. Consumers make choices every day but they are not free to choose if they are not allowed full access to the existing scientific information which could

affect their choice. Restriction of information is an attempt to force a particular choice on the consumer and results in consumers having no real choice at all. With full access to available information consumers are then free to decide for themselves instead of being manipulated by their government or by product suppliers. Consumers may even make a choice to ignore the available information. That is their right. As long as consumers have full access to the information supporting or discrediting a health claim they should be allowed to hear the health claim and make their own informed choice. Thank you very much for allowing me to speak here today.

[Applause]

MS. FRASER: Thank you, Mr. Quinn. Someone left a very nice pen here. So, whichever speaker this belongs to, it is here at the end of the day. Our next speaker is Mr. Don Bodenbach, CEO of Frutaiga. Is he present?

PARTICIPANT: No.

MS. FRASER: Then we will have Miss Alison

Kretser, Senior Director, Scientific and Nutrition Policy with the Grocery Manufacturers Association. Thank you.

MS. KRETSER: Good afternoon. GMA commends FDA for holding this public meeting to consider the agency's research to assess consumer perceptions of health claims for food products. The research that has been done to date provides useful background information for the additional work that must be undertaken in order to better implement qualified health claims on the food label.

The consumer research that so far has been conducted on disclaimers for qualified health claims has been very narrow in scope. While the results of this research are useful in determining that the proposed report card grades have unintended adverse effects and that sentences using closely related adjectives do not allow a number of consumers to correctly distinguish among the four categories tested, the research has not explored more effective ways of conveying this information

to consumers.

The research does not demonstrate that no form of statement can be devised to provide a higher level of consumer understanding of the strength of the health claim. Rather, the research thus far has shown only that the specific approach suggested by FDA in its July, 2003 guidance is not functioning adequately in this regard. There is a wide variety of alternative approaches that should be considered.

For example, it is apparent from the consumer research that four levels of qualified health claims are too many. However, more importantly, we learned from the consumer research that qualified health claims should not exist in a vacuum, separated from unqualified health claims. We must look at them as a continuum. A consumer should be able to easily understand the difference between an unqualified health claim and a qualified health claim. Today, the interim system lacks this cohesiveness.

Additional research should test the

possibility of having two tiers or, at most, three tiers of health claims. For example, one tier for unqualified health claims and two tiers for qualified health claims. Although the best wording to use to distinguish among such tiers must be the subject of future research, GMA offers the following examples to illustrate the concept of a three-tier system:

For an unqualified health claim, very strong science demonstrates that calcium helps reduce the risk of osteoporosis. For the first tier for qualified health claims, strong science suggests that nuts may help reduce the risk of heart disease. For the second tier for qualified health claims, weak science suggests that green tea may help reduce the risk of prostate and breast cancer.

As previously noted, there must be a continuum across both types of health claims. Industry today is reluctant to use the required language of unqualified health claims because it is so burdensome. Simplification of these claims

would improve the chances that a consumer would more clearly understand the relationship between the claim and the product itself and, thus, be motivated to make dietary changes.

Health claims on food labels, including both qualified and unqualified health claims, can make a significant contribution to the public health. It is important to remember that labels are capable of reaching all consumers, even those who do not have access to other nutrition information and who carry the greatest burden of chronic disease in this country.

At the recent ADA annual meeting FDA pointed out that the food label is the third jewel in the crown of nutrition policy, the dietary guidelines and my pyramid being the other two. GMA believes the food label as a whole, and unqualified and qualified health claims in particular, are critical tools that can be used to communicate the government's nutrition messages detailed in the authoritative dietary guidelines.

As FDA conducts future research to

determine the most effective language for qualified health claims, GMA recommends that it also include unqualified health claims. The agency should recognize that changes in the rules for unqualified health claims may be a necessary part of the decision. The whole concept of health claims, qualified or not, is to provide consumers with accessible information they can and will use to improve their diets. Thank you.

[Applause]

MS. FRASER: Thank you, Miss Kretser. Our next speaker is Richard Renton, President of Northwest Nutraceutical. Welcome, Mr. Renton.

MR. RENTON: Everyone is such a good speaker here, I am embarrassed to be up in front of all of you, but I would like to take this opportunity to make a few public statements. My name, again, is Richard Renton and I am President of Northwest Nutraceutical, which is a relatively small dietary supplement manufacturer. I have a science degree and decades of experience in consumer education about the role of dietary

ingredients in human health.

Is it surprising to anybody that emerging science like nutritional science gives differing opinions throughout our society, whether it is the consumer or scientists themselves? The current way that health claims are done reminds me very much as a scientific journal that we are allowed to read the first two sentences of the abstract and then the editor gets to make comment and, if we are lucky, we get to see some references at the end. I think the way to direct is not to not limit the science but make it available.

I would like to see studies with people that have the opportunity to read additional information on the benefits of nutritional supplements, whether they are in the form of supplements or food, and then make a decision. I am also very concerned about this report card system in that, in first impressions, I feel that many people will also associate those grades in the quality and purity besides just the science. That concerns me as a manufacturer since we have

very high standards.

I would also like to see as far as the studies--I see that people who take dietary supplements, they all eat. But people that eat don't all take dietary supplements, and the majority of the studies that I have seen today were based on food products. I would like to see some of the studies move forward--I don't know what you would call them, mall hunters, stand outside supplement supply stores and ask them the same questions and see how the results vary. I think the people that are interested in this science will be interested in reading all the science and not just be limited.

The solution to this isn't less information; it is more information. If the consumer wants to understand the nature and the extent of the science, they will. It is not our job to determine what amount of information they want, nor is it FDA's. Thank you very much.

[Applause]

MS. FRASER: Thank you, Mr. Renton. Next

we will hear from Arline Brecher, speaking on behalf of herself. Thank you.

MS. BRECHER: Thank you for the opportunity. I have been introduced to lots of audiences and many radio programs and seminars, but never before as a consumer. But I will take advantage of that because I am going to give you a consumer's experience with nutritionals as kind of, I hope, a shocking story in a way.

My husband and I are medical writers, researchers, publishers, five best selling books, starting in 1974 with psychodietetics. Our most recent one, we did "Bypassing Bypass and 40-Something for Ever"--huge, huge sales, and so became rather well-known as interested and knowledgeable about cardiovascular nutrition. April, 2001 a huge shock--my husband suddenly--and we walk the talk; we don't do anything different than what we talk about and write about--came down with the most serious case of congestive heart failure you can imagine. Every terrible diagnostic guide showed that he had a very short time to live.

And, we didn't know what to do because, much as we know about chelation and non-invasive treatments for atherosclerosis, we knew nothing about congestive heart failure except that everybody was talking about the ten deadly drugs that my "deep throat" innovative FDA person had been talking to me about for 17 years, and gave us all the information about the deadly effects of cardiovascular drugs that made up a chapter he wrote anonymously for cardiovascular disease.

So, we knew better than to rely on those drugs, and knowing no place to go to get the advice we needed, we called him and he had lunch with us, very close to this building, and we asked him what to do. And, I will tell you what he said. He said, well, he is very sick and he is drowning and until you get a doctor who will treat him the way you want him to be treated, I will take him under control. I will get him a prescription for the safest diuretic I know, and I will monitor his blood and his cellular levels until you find somebody else. I said, okay, what else?

He said two things, number one, keep him away from cardiologists. Number two, no other drugs. It was really what we wanted to hear and I

guess we needed his permission, 35 years with the FDA, to do what we wanted to do. And, I said what will we do? He laughed and he smiled and he said you will find a way. And we did.

And I want to tell you about that way as a consumer. Being very active as a health freedom activist, nutrition writer, medical researcher and writer, with three web sites, lots of exposure, I knew all the right doctors to get in touch with. I told them what happened with Harold. It was not until two years later that we found out what made him so sick. And, this gets right to the topic of today's discussion--labeling information. As a wonderful, knowledgeable, interested wife I had almost killed my husband because of a labeling defect I had not even thought of to check. He was found to be loaded with mercury. From what? From the 3,000 mg a day he had been getting for eight years that was not certified mercury free. That is

what needs to be on the labels, information that will keep people out of trouble and know that the products they are getting will help because they are properly--properly manufactured.

So, all the doctors we contacted, all the researchers and all the biochemists, everyone who knew us and loved us came forward and Harold's decision was I will do whatever you find that is supported by independent research, not manufacturers' claims, not testimonials but independent research. And, what do you know? The congestive heart failure, the leading family disease killing Americans more and more every year--there are well researched, documented substitutes in the nutritional protocols for every toxic drug. And we put the protocol together and gradually--gradually his congestive heart failure, a terrible disease as you all know, gradually Harold got better.

How much better? He rides his bike every day, even when it is 55 degrees, to Reston community center and back and 16 miles on Sunday to

go to church. The man who couldn't walk from the back of the house to the front of the house four years ago now runs up and down three flights of stairs. I beg the FDA and everybody who has made these comments to let this information out to people to help them save lives, to save money, to save our security. Thank you. [Applause]

MS. FRASER: Thank you Mrs. Brecher. Our next speaker is Rich Marino, President of En Vigra Liquid Supplements.

MR. MARINO: I too would like to thank everyone here for the opportunity to speak to you all about what is important to me. I guess, under the impression of what I was coming here for, I wasn't thinking as much of the labeling claims but as far as the ability to speak openly with consumers.

As said, my name is Rich Marino and I am President of En Vigra and I own a vitamin company. The necessity for me to do that came from two-fold. One, my father, since I was five years old, has had heart disease, heart attacks, cancer, prostate

cancer, colon cancer and I have seen his life and him as a person dwindle and dwindle and dwindle. The entire time as we were going through all this, the doctors preached nutrition and exercise; nutrition and exercise. Here are some medications. They may help as a crutch. They may assist you but the reality of it is, John, you have to change your lifestyle.

In doing so, that is what drove my passion for health and wellness. In the past years I started as a physical trainer and then owning the company and then having four years on the radio. I speak to consumers a lot. There is an overwhelming amount of people who are looking for other solutions out there but, by suppressing the information, it is difficult for me to say--because I follow your laws and rules to a T as a law-abiding citizen; I respect what you do and I don't envy what you do here. Trust me, I imagine it has to be very difficult. But it is hard for me to have an honest conversation because now by law I am not allowed to have an honest conversation with

somebody that says to me, Rich, I have been to my doctor. They say surgery is the answer. They say these prescription medications are the answer. But I know what happens with surgery; I know the risks. I also know the risks of taking the drugs. Yet, I don't want to do that. I am looking for other solutions.

We will take osteoporosis and the glucosamine chondroitin for example. I cannot convey to them that this might be another solution for them. All I can say, and all I ever do say is just try our products and see what happens. But it pains me to listen to their pleas for the information and they are starving for the information. So, in allowing qualified claims, in allowing the disclaimers I believe that the FDA can further police that effort because then you will see where the truthful information is coming from, from which companies, and then you will also be able to disseminate where the crooks are.

In my experience, I have used several different supplements that I had very bad side

effects from so I can speak from experience that it definitely does need policing. And, I believe that by getting the information out there and allowing people to make their decisions on their own, you have a stronger ability to, again, protect the safety of Americans.

One question that I have for you in all of the research that was talked about today--it was all done on dietary supplements and opinion on dietary supplements, has any of that same information been done, and what I encourage you to do--is the same type of studies with over-the-counter drugs? I would assume that with the over-the-counter drugs disclaimers, the box claims, you would find very, very similar results. Again, I thank you for your time.

[Applause]

MS. FRASER: Thank you, Mr. Marino. Our next speaker is Dr. Annette Dickinson, former President of the Council for Responsible Nutrition. Dr. Dickinson?

DR. DICKINSON: Thank you very much. As

many of you know, I retired earlier this year to Minnesota and so I am speaking today as an individual, as a consultant to the dietary supplement industry on issues relating to scientific and regulatory affairs, and including health claims.

I do believe that health claims, including qualified health claims, have great potential to communicate useful health information to consumers. The challenge, of course, as we have been discussing all day, is how to convey complex information in a manner that consumers can understand.

We know that identifying multiple levels of qualified health claims, as FDA has done, may be very useful from a regulatory point of view and as a means of aiding scientific review. But I do not believe we should expect, or can expect, that consumers necessarily need to be able to detect all those gradations of evidence that may, in fact, be relevant to regulators and to the industry.

I want to mention just two thoughts that

come to me on the basis of the research that has been presented here today. The first is that distinctions between some claims categories are not, in fact, based at all on level of evidence of support. We have talked here today to some degree about NLEA health claims, about dietary guidance, about nutrient content claims and about structure/function claims. These claims differ in kind but not necessarily in the degree of scientific evidence that supports them. The strength of the evidence for each of these types of claims may be entirely equivalent and, in fact, may be stronger for some structure/function claims, for example, or nutrient content claims than for some health claims. Therefore, it is not surprising when consumers give them equal credence and, in doing further research, we should accept the notion that consumer may, in fact, rightly equate some structure/function claims with fully approved health claims or even with qualified claims.

My second comment is that within the category of health claims qualified health claims

must, of course, be qualified to avoid misleading consumers, but that may not require that consumers themselves exhibit an ability to rank various levels of claims to the complete degree that regulators do or that scientists do in evaluating the evidence. Importantly, given the current system for qualified health claims language and for fully approved health claims language, there is currently, as has already been observed today, no signal for consumers internally within the fully approved health claim regarding the strength of the evidence that supports a fully approved health claim. The mere absence of qualifying language in a full approved health claim is clearly not a sufficient signal and does not allow consumers to identify these claims as having the strongest support.

Therefore, in future research, whether consumers are exposed to linguistic clues as signals or are exposed to letter grades as signals, I believe it is important that the signals must be present in the fully approved claim as well as in

the qualified health claim, otherwise the consumer cannot be expected to be able to rank such claims based on the strength of the evidence.

Additional consumer research should more fully explore various ways of conveying this information for the full spectrum of claims and for all types of claims that are available to consumers in deciding what products they will choose to support their health. Thank you.

[Applause]

MS. FRASER: Thank you, Dr. Dickinson. Thank you all for your continued attention. You know, the ones that come later have the harder task and I appreciate all of you being attentive and listening and according each person the same respect. So, my thanks to you on behalf of FDA. Our next speaker is Dr. Iona Carabin, President and Medical Director of the Women's Health Sciences Institute.

DR. CARABIN: Good afternoon. Women's Health Sciences Institute is a 501(c)(30 not for-profit organization, located in Florida. I

appreciate the opportunity to present today and convey one view of women's perception on the labeling of qualified health claims.

In the United States the trend continues to shift from traditional medicine to complementary and alternative medicine. Prevention through better dietary intake, regular exercise and the use of herbal and dietary supplements has taken center stage. In 2003, in an effort to protect consumers, FDA introduced the interim procedures for assessing qualified health claims based on the strength of supporting scientific data.

The new regulations were anticipated to provide consumers with better information and aid them in making informed decisions regarding the efficacy of dietary supplements. Instead, the regulations generated more incertitude and confusion among consumers than ever before. Over the last several years research showed that a large percentage of consumers interested in using herbal and dietary supplements are comprised of women, and dietary supplement use is high across all ethnic

groups and tends to increase with age.

In reality, these represent staggering numbers considering that of 281.4 million people living in the United States in 2002 51 percent are women. Of this number, 29 percent of women are members of racial or ethnic minority groups. The interest that women have in dietary supplement use is mainly generated by two distinct drives. One has to do with women's concern with their own complex physiology and aging issues, while the other is related to disease prevention as generally women feel responsible for the health and well being of their families.

However, as the rest of the consumers, women have difficulty making decisions regarding the efficacy and purchase selection of dietary and herbal supplements, and the question is why. Simply put, it is because FDA's interim guidelines for qualified health claims and the method of categorizing the claims into B, C or D provide consumers with convoluted wording on the label and no real meaning. The obtuse language that the

agency utilizes to summate the scientific data limits consumers' freedom of choice and obscures useful information.

The current situation leads to a peculiar state of affairs where consumers are not inclined to select products that do not make claims or those that make structure/ function claims over those that make qualified health claims. It is evident that dietary and herbal supplements remain of great interest to the American public. However, the public wants to see guidance and helpful information from the FDA in language that everyone can understand. In fact, the FDA requires the use of plain language by the drug and medical devices industries on pamphlets, patient inserts and brochures. Why not have FDA follow the same requirement it imposes on other industries? Providing consumers with straightforward and easy to understand information can be easily accomplished by, one, continuing the use of the existing health claim classification system, that is, significant scientific agreement, qualified

health claim and structure/function claims, two, completely eliminate the lettered grading and wording currently used for qualified health claims and, three, as a means to inform the public of the final decision FDA makes following review of a qualified health claim petition, a no objection statement should be placed on the label and be used in advertising. This completes my comments. Thank you for your attention.

[Applause]

MS. FRASER: Thank you, Dr. Carabin. Our next scheduled speaker is Dr. Berna Magnuson, toxicologist at the Burdock Group, and she does have a graphic that is up on the screen. Thank you.

DR. MAGNUSON: Thank you. I am Berna Magnuson, with the Burdock Group. We are consultants to the food industry on food and ingredient safety, claims and labeling issues. I have three separate points to make today.

The first one is to propose an alternate signaling graphic, which you see in front of you,

to communicate the integrity and strength of science for particular claims. The second is to discuss a change in the approach to evaluating the strength of science of health claims. The third is to suggest a period of proprietary use of information for health claims.

My first point, recent data on the difficulty consumers have in understanding health claims, qualified health claims and structure/function claims really confirms the experience that I have had trying to teach nutrition students, interested consumer groups and individuals in the food industry about the different types of claims. People just do not know that there are different scientific criteria for and different meanings behind the different types of claims that are present on foods. We are proposing a simple graphic, such as you see above you, to communicate the difference in terms of the strength of science. This parallels similar kinds of strength messages or symbols that we see on food right now, similar to strength of your coffee,

strength of the spiciness of your salsa--I am not trying to diminish this, the importance of scientific information to spiciness of salsa, but it does show you in terms of the relativeness and it illustrates, as we have mentioned before, the difference between all three different types of claims. It will tie these together and we recommend this be used in combination with the wording to more simply illustrate the decreasing level of science and comfort with these claims.

My second point, with the accumulating evidence that consumers do not understand and, therefore, may not value health claims, incentive for food producers and manufacturers to invest in the necessary research to demonstrate efficacy of their products is dwindling. The food industry is frustrated with the lack of clear guidance on what data is actually needed for health claims and is concerned that dollars spent on research studies may not provide a market advantage. We propose use of expert panels, a model that is currently used in the generally recognized as safe notifications, to

broaden involvement of experts in the scientific community and to provide further clarification and understanding of the process of grading health claims.

The use of expert panels presents advantages to FDA, to the food industry and to consumers. For the FDA, the use of expert panels would result in the submission of a detailed dossier outlining the concept of the health claim, the necessary information on the food or food ingredient, background on the disease and a critical evaluation of the scientific evidence in support of the claim. Thus, the burden of compilation of scientific data needed for the claim would be shifted from FDA to the petitioner and the expert panel. We have heard today that there is currently a major bottleneck in this regard so perhaps moving some of that out of FDA into the scientific community would help to alleviate that.

For the food industry, use of expert panels is a familiar concept based on the GRAS affirmation process. Use of expert panels would

allow the health claim process to be more transparent as it would be taken out of the halls of FDA and moved into the community of science, with FDA still having final approval and review. If industry has more confidence and understanding of the process of qualified health claims, they will be more likely to invest the dollars in the research needed to have those approved.

My last point is that a period of proprietary use of at least some of the data that is generated by the industry and supplied to FDA to support the health claim is needed. A provision for confidentiality for industry reports for a specific period of time would allow some time for the petitioners to have proprietary use of that data and provide a market advantage. Again, this is in order to provide an incentive for the industry to invest in these very expensive clinical trials that are currently required for high level health claims. This is an opportunity for the industry to obtain a return on investment.

How do these last two points affect

consumers? Consumers will be the losers--seeing as how I am the last one, I am just going to keep going--consumers will be the losers and ingredient industries will abandon research to support health claims. We have heard evidence is great in terms of the impact of diet on health and we must continue to work to develop a system that provides incentive to food manufacturers to improve their products for health and to communicate this clearly to consumers. Thank you.

[Applause]

MS. FRASER: Thank you, Dr. Magnuson. You were still within the 20 seconds. You were fine. Thank you to all of our commentors. We appreciate the input and the feedback. We have about an hour remaining and I would like to see, by a show of hands, how many people who have not yet had an opportunity to speak may be interested in providing comment to FDA. One. Any others?

[No response]

Well, I will ask the gentleman who did raise his hand to come forward and state your name

and affiliation for the record. Thank you and welcome. And, I will still abide by the same five-minute rule in fairness. Thank you.

MR. SECKMAN: Thank you. Thanks for the five minutes. I appreciate that too. I am David Seckman. I am the Executive Director of the National Nutritional Foods Association. NNFA is a trade association representing the interest of more than 8,000 retailers, manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products in the United States.

NNFA strongly believes that the use of health claims can benefit both manufacturers and consumers, and as a trade association representing nutritional foods, we believe that health claims can be an effective marketing tool for those manufacturers and distributors of "good for you" food products. At the same time, health claims can offer important information in food choices for consumers seeking those foods.

According to a health and wellness trends report published last year, the majority of

consumers, 61 percent, agree that it is important to have foods that bear a specific health claim. More than two-thirds also agree that printed health claims make purchasing decisions even easier for them. As the number of foods available for health claims steadily increases, FDA should be providing consumers with the comprehensive information they desire to make decisions about the foods they need and want.

Unfortunately, the verbiage adopted by the FDA for both the full and qualified health claims results of the information being under-utilized despite strong consumer demand. Manufacturers find the health claims language cumbersome and even conflicting. In addition, the qualified health claim language adopted by the FDA in most cases, including what was stated in the working paper, does not reflect the specific state of the science. Rather, this language is standardized to fit a few defined scenarios based on the level of science submitted. As a result, consumers are either being confused by the wording of the claims or are not

being provided with the health claim information.

In addition, NNFA believes that the FDA's assessment of consumer perception, made available in the context of this request for comments, confirms that this qualifying language used by the FDA most frequently to date is unhelpful to consumers. FDA has not, however, tested other possible disclaimer language adopted by the FDA in some of the most recent qualified health claim scenarios which may be more meaningful, relevant to the state of the science and ultimately of more use to consumers seeking this information.

NNFA also believes that manufacturers are hesitant to request a health claim because they feel the response time is simply too long. NNFA urges the FDA to spend the resources necessary for timely review in allowance of health claims, otherwise the entire health claim process frustrates ingredient development and marketing decisions for those seeking to entertain their use.

Since all of us are familiar here with Pearson versus Shalala, I won't really go into

detail since it has been discussed at great length, however, it is important to note that the court in Pearson described the types of disclaimers that it felt would be meaningful for consumers. The court recommended very ingredient specific language, tailored to the scientific presentations made by the petitioner. It did not recommend a standard recipe of disclaimer language that would be triggered when a certain level of science was presented, which is what the FDA has since that time imposed on most petitioners seeking health claims.

During Pearson, the FDA argued to the court that the type of disclaimer recommended would cause consumer confusion, yet the agency offered no consumer data or evidence that it did. Now FDA makes a request to industry to provide the type of evidence it lacked in the Pearson case and continues to lack today.

FDA supports this request with a working paper on the effects of strength of science disclaimers on the communication impacts of health

claims. The study used two verbal schemes and two report card grade systems to express the disclaimer language. However, all three use the same four-level system to classify the health claim systems in terms of the strength of the science, and includes the same standardized disclaimer language utilized most often by the FDA for qualified health claims.

The study found that the text sentences using adjectives do not correctly convey the intended strength of the science and that the report cards, while addressing the strength of the science, cause greater confusion as to the perception of the scientific certainty relative to the unqualified claims. The study did not explore the types of ingredient or science-specific disclaimers directed by the Pearson case.

NNFA believes very strongly that consumers do not understand the disclaimer language stated by the FDA because it is too qualified and not specific enough. FDA should have explored this with the type of disclaimer suggested by the court.

In NNFA's view it is likely that the consumers would have understood and appreciated that type of claim. We believe that consumers would welcome educational disclaimer language that is relevant to the ingredient and the science of that ingredient rather than standardized language that is vague and unclear.

In terms of the educational element, another recent study also acknowledged the value of helping consumers understand and seek out health claim information on food labels. NNFA echoes these goals. Education is a known component to any new regulatory scheme. Without it, consumers are left in the dark as to why, for example, one claim bears a disclaimer and another does not or why the disclaimer language is different.

Whatever the FDA decides to do in terms of the procedures by which it will review health claims and approval and exercise enforcement discretion, and however the agency ultimately phrases these claims, consumer comprehension is tightly linked to an educational component. Thank

you.

[Applause]

DR. WILLIAMS: Let me just say that I want to reiterate what Dr. Bradbard said this morning. We are doing some additional testing on claims and we do welcome your written comments following this meeting for the next 90 days on any additional consumer research--60 days, excuse me--that you think would be helpful for us to do, to inform FDA as to where we should proceed with our policy from hereon in.

Wrap-up Summary

MS. FRASER: Thanks, Rich, and thank you to our last speaker. Are there any second choices? Anybody else want to give any comments to FDA? Promise not to let any of your fellow attendees shoot you for standing between you and freedom!

[No response]

Well, with that, I have a few brief closing remarks. I won't take the full 15 minutes, for sure. I want to thank in particular our presenters for today who came and presented their

consumer research, not only our own Dr. Brenda Derby but in particular those who came from near and far, Dr. Pauline Ippolito, Wendy Reinhardt Kapsak, Dr. Paula Fitzgerald Bone, Dr. Karen Russo France and Dr. Neal Hooker. If we could give them another round of applause--

[Applause]

We will have copies of the presentations in our docket if you want to obtain versions of those in addition to the handouts that you have. I also want to thank Marion Allen for doing all of the hard logistics of getting this meeting up and running, and all of the consumer studies scientist staff who greeted you out front, and others up in the booth. You know, it is all the people who kind of do the nitty-gritty details that make the thing go smoothly and make it easier for me. So, I appreciate all of their efforts.

Certainly, I want to thank each and every one of you for attending, for taking the time to attend this important meeting. I want to thank those of you who provided oral comments here and

for sharing your thoughts with us. Those are very important as we move forward and make decisions and give input to the policy makers, and we do encourage further written comments to the dockets, either what you have said here or otherwise.

So, again, thank you. Have a wonderful Thanksgiving and a safe journey home.

[Whereupon, at 3:23 p.m., the proceedings were adjourned.]

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